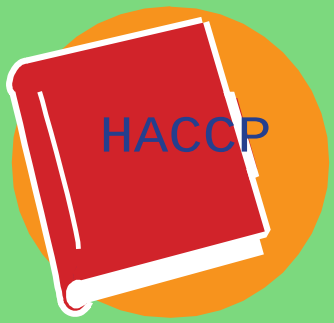
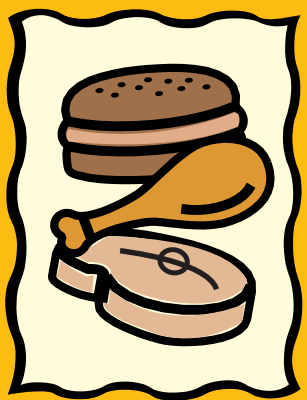
Your Self-Study Guide To Understanding How To Develop A HACCP Plan





To help you meet the training requirements 9 CFR 417.7 and to provide technical guidance for you in the development of your HACCP plan.

Published by Technology TEAM, Incorporated.

Requests for permission or further information should be addressed to:

c/o HACCPWORKS
Technology TEAM, Incorporated
5501 Cherokee Avenue
Alexandria, VA 22312
http://www.tteam.com/

Table of Contents

Your Self-Study Guide to Understanding How to Develop a HACCP Plan

Section 1

How to Use These Materials

The Goal

To help you meet the training requirements of 9 CFR 417.7 and to provide technical guidance for you in the development of your HACCP plan(s).

What You Will Find in this Package

Books

Manual - "Your Self-Study Guide to Understanding How to Develop a HACCP Plan"
(includes Review Questions)

Appendices in Manual

- Blank Developments Form and Logs
- HACCP Systems Basic Compliance Checklist
- Regulations 9 CFR Part 417

Videos

"HACCPWORKS" *(Complements the manual)*

"HACCP: The Hazard Analysis and Critical Control Point System"
(The free video on the seven HACCP principles was produced by the Minister of Public Works and Government Services, Canada, 1996.)

Letter of Completion *(Complete and submit when done)*

Completion of the following items will fulfill the training requirement of 9 CFR 417.7

1. Thoroughly read this manual.
2. Complete the Review Questions in sections 3 and 4 of this manual.
3. Submit a letter indicating that you have completed the 2 requirements listed above to:
   HACCPWORKS
   P.O. Box 22857
   Alexandria, VA 22304
   or FAX to 1-800-123-4567
4. Prepare a draft HACCP plan for one of your products or processes that addresses all the requirements in 9 CFR 417.2, the Hazard Analysis and the HACCP Plan. Then submit the draft HACCP plan to HACCPWORKS, **at the address given above**, for review and comment, to the above address. We encourage you to use the generic HACCP models that best suit your products or processes as a guide. You may submit up to two draft plans. HACCPWORKS will verify whether your plan has or has not addressed all the requirements and then inform you by the letter the results of their analysis. HACCPWORKS will not approve your plan. However, they may make suggestions on how to improve it. Communications between the participants and HACCPWORKS will be through a variety of methods including: mail, e-mail, fax and a toll-free telephone support line.

5. Upon successful completion of steps 3 and 4 above, HACCPWORKS will send you a letter acknowledging your satisfactory course completion.

This package of materials has been designed to assist you in understanding how a HACCP system is developed and implemented. Additional materials have also been included that will serve as helpful reference materials.

This Manual explains the concepts of HACCP, and shows you how to fill out the forms associated with each step. The Manual covers three topics:

1. The Preliminary Steps.
2. The Seven Principles of HACCP.
3. How to Implement and Manage a HACCP System.

How to Use these Materials

1. View the "HACCP: the Hazard Analysis and Critical Control Points System" video
2. View the "HACCPWORKS" video.
3. Read the manual. *(We recommend that you take each section and spend one day reading information and working through the review questions.* ***Don't try to do it all in one day****. You'll find that the more time you give yourself to prepare, the easier HACCP will be).*
4. Read and Answer the "Review Questions" after Sections 3, 4, and 5. *(Two pages have been set aside for you at the end of each section for note taking. The notes you take should help you answer the review questions.)* Compare your answers with the answers and explanations provided in Section 6. *(Feel free to work with the review questions for as long as you feel necessary).*
5. Review the generic HACCP model that is appropriate to your process or product.
6. Prepare a HACCAP plan and submit for review.

Where to Get More Information

- HACCPWORKS: (877) 422-2799
  Web site: http://www.tteam.com/haccpworks/
  e-mail: haccpwx@tteam.com
- FSIS Web site: http://www.usda.gov/fsis/
- FSIS Technical Service Center (800) 233-3935
- USDA Meat and Poultry Hotline (800) 535-4555
- Office of the FSIS National HACCP Small Plant Coordinator (202) 720-3219
- National Agriculture Library/USDA
  (301) 504-6365; fax: (301) 504-6409
  e-mail: foodborne@nal.usda.gov
- International Meat and Poultry HACCP Alliance (409) 862-2036
  Web site: http://ifse.tamu.edu/haccpall.html

How to Order Generic HACCP Plans and Guides

Generic HACCP Plans and Guides (Drafts)

___HACCP-1 Guidebook for the Preparation of HACCP plans
___HACCP-3 Generic HACCP Model for Raw, Ground Meat and Poultry Products
___HACCP-4 Generic HACCP Model for Raw, Not Ground Meat and Poultry Products
___HACCP-5 Generic Model for Poultry Slaughter
___HACCP-6 Generic HACCP Model for Mechanically Separated (Species)/ Mechanically Deboned Poultry
___HACCP-7 Generic HACCP Model for Thermally Processed Commercially Sterile Meat and Poultry Products
___HACCP-8 Generic HACCP Model for Irradiation
___HACCP-9 Generic HACCP Model for Meat and Poultry Products with Secondary Inhibitors, Not Shelf-Stable
___HACCP-10 Generic HACCP for Heat Treated, Shelf-Stable Meat and Poultry Products
___HACCP-11 Generic HACCP Model for Not Shelf-Stable Heat Treated, Not Fully Cooked, Meat and Poultry Products
___HACCP-12 Generic HACCP Model for Fully Cooked, Not Shelf-Stable Meat and Poultry Products
___HACCP-13 Generic HACCP Model for Beef Slaughter
___HACCP-14 Generic HACCP Model for Pork Slaughter
___HACCP-15 Generic HACCP Model for Not Heat Treated, Shelf-Stable Meat and Poultry Products

Name: _____
Organization: _____
Address: _____
City: _____ State: _____ Zip Code: _____
Phone: _____ Fax: _____
E-mail: _____

To obtain free copies, please fax this form to (202) 690-0824 or mail to:

Food Safety and Inspection Service
U.S. Department of Agriculture
Room 202-Annex Bldg, 300 12th St., SW
Washington, DC 20250-3700
(202) 720-3219: Fax (202) 690-0824

Section 2

Introduction to Food Safety and HACCP Systems

HACCP Definitions

§ 417.1 Definitions.

Corrective action. Procedures to be followed when a deviation occurs.

Critical control point. A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical limit. The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate or reduce to an acceptable level the occurrence of the identified food safety hazard.

Food safety hazard. Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

HACCP System. The HACCP plan in operation, including the HACCP plan itself.

Hazard. See food safety hazard.

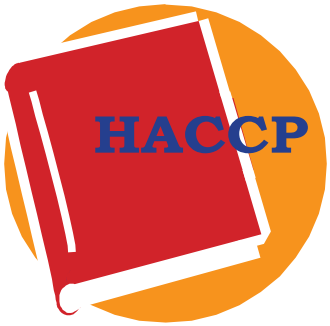
Preventive measure. Physical, chemical, or other means that can be used to control an identified food safety hazard.

Process-monitoring instrument. An instrument or device used to indicate conditions during processing at a critical control point.

Responsible establishment official. The individual with overall authority on-site or a higher level official of the establishment.

Origin/History of HACCP for Meat & Poultry Plants

The HACCP requirement and other food safety measures required by FSIS in the Pathogen Reduction/HACCP Final Rule were motivated by the critical need to fill a gap in the regulatory system and a need for adequate measures to address the problem of pathogenic microorganisms on meat and poultry products.



FSIS believes its food safety goal should be to reduce the risk of foodborne illness associated with the consumption of meat and poultry products to the maximum extent possible by ensuring that appropriate and feasible measures are taken at each step in the food production process where hazards can enter and where procedures and technologies exist or can be developed to prevent the hazard or reduce the likelihood it will occur (60 FR 6785.)

An Introduction to the Preliminary Steps

The development of a HACCP plan is a logical step by step process. Each step builds on the information gathered from the previous step. The process works better if you take some preliminary steps. We have included five. You may wish to use the example forms located in Appendix A; or you may wish to create your own forms. This would be a good time to begin working on your HACCP plan.

1. Assemble the HACCP Team.

The first thing that must be done is to bring together individual(s) in your plant who have a working knowledge of the various processing steps and operations of your plant. This group will be your "HACCP team."

2. Product/Process Description.

Next, the HACCP team will describe each of the products being produced by its common name, how it's packaged, its labeling instructions, its shelf life, where it'll be sold, how it'll be distributed, and how it'll be used by the consumer. Remember you may group all your processes that are in the same

category using a single HACCP plan. There are nine process catagories into which meat and poultry production can be grouped; they are:

- Slaughter - all amenable species
- Raw product - ground
- Raw product - not ground
- Thermally processed - commercially sterile
- Not heat treated - shelf stable
- Heat treated - shelf stable
- Fully cooked - not shelf stable
- Heat treated but not fully cooked - not shelf stable
- Product with secondary inhibitors - not shelf stable

3. Develop a List of Ingredients & Raw Materials.

The third step is for the team to thoroughly review each product and write down all of the ingredients and raw materials.

4. Develop a Flow Diagram.

At the fourth step, the HACCP team will draw a flow diagram that shows all the steps in the production process (everything from receiving through distribution.)

5. Verify the Flow Diagram.

The final step is to take this flow diagram and verify its accuracy. The HACCP team can do this is by having an impartial person do a "walk-through" of the entire production process, checking to see if there is anything missing from the diagram. This should be someone who knows or is familiar with the production process.

§ 417.2 Hazard Analysis and HACCP Plan.

"(b) *The HACCP plan*. (1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur..."

[After these 5 preliminary steps are complete, you'll take all of the information the team collected and use it to fulfill the requirements of the seven HACCP principles.]

An Introduction to the 7 HACCP Principles

Principle 1: Conduct a Hazard Analysis.

The hazard analysis looks at different factors that could affect the safety of your food. This analysis is done for each step in your production process. It's important to remember that you are dealing with ***safety, not quality*** issues.

The hazard analysis is actually completed in two stages. The first stage identifies food safety hazards that are present in your process. The second stage evaluates these food safety hazards as to whether they are ***"reasonably likely to occur."*** If the HACCP team decides that a food safety hazard is likely to occur, then they need to find and list any preventive measures that could be used to control those food safety hazards. Preventive measures are defined as ***"Physical, chemical, or other means that can be used to control an identified food safety hazard."***

Ingredient Related Hazards

As you evaluate the hazards in your process, don't forget about ingredient related hazards. Everything that goes into your product needs to be evaluated. Ingredient specifications, provided by your supplier, should give you details on the materials/ ingredients being sold, including statements that the materials/ingredients are of food grade and are free of harmful components. For example, the ingredient specification for dried legumes (beans) might state that there will be fewer than 5 small rocks or stones per ten pound bag and that no harmful pesticides were used in the growing process.

Principle 2: Identify Critical Control Points (CCPs).

A critical control point is defined as ***"A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels."***

The HACCP team uses the list of food safety hazards and preventive measures they developed during the previous hazard analysis step to determine their critical control points. CCPs may include, *but*

are not limited to:

- Chilling or freezing
- Cooking
- Certain processing procedures *(such as filling and sealing cans)*
- Certain slaughter procedures

Steps that are CCPs in one facility *may or may not* be CCPs in your plant. When making a HACCP plan, each plant must look at the unique conditions present in that plant.

Principle 3: Establish Critical Limits for Each CCP.

A critical limit is defined as ***"The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard."***

Critical limits serve as boundaries of safety for each CCP. Often they are a numerical value (whether that is temperature, pH, etc.) that must be reached to assure that a food safety hazard has been controlled.

Resources for determining your own critical limits may be found in regulatory standards and guidelines, scientific literature surveys, and other food safety hazard reference materials.

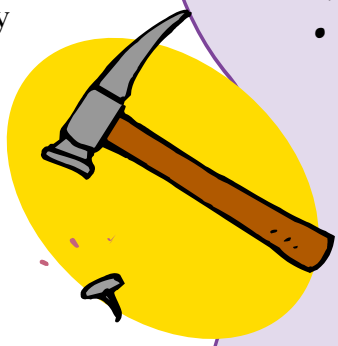
[A note about Critical Limits – If your HACCP team does establish critical limits for your specific facility, know that those limits may never be less strict than the current regulatory standards.]

Monitoring Requires Precision

Monitoring a CCP is a big responsibility. Employees must be properly trained and need to understand the reasons for careful monitoring procedures.

Specify in your monitoring procedures every important detail about...

- Who will do the monitoring
- What is being monitored
- When it is done, and
- How it is done



For example, when taking the temperature of a piece of meat, be specific as to where on the carcass you took the temperature.

Remember that all records and documents associated with a CCP's monitoring should be dated and signed or initialed by the person doing the monitoring and the results recorded.

Principle 4: Establish CCP Monitoring Procedures.

Monitoring is a fundamental part of any HACCP system. It consists of observations or measurements that check to see that your CCPs are operating under control. **Monitoring serves three main purposes:**

First, it tells you when there's a problem at a CCP, and control has been temporarily lost. *(This allows you to take corrective actions right away.)*

Second, it tracks the system's operation and can help identify dangerous trends that could lead to a loss of control. *(This allows you to take preventive action to bring the process back into control before it goes beyond the critical limits.)*

Third, it provides written documentation of your compliance with the HACCP regulation. *(This information can be used to confirm that your HACCP plan is in place and working right.)*

For each CCP the HACCP team will need to find the monitoring procedure and its frequency (hourly, daily, weekly, etc.) that best tracks that CCP. It's also important to thoroughly train the employee(s) that will be responsible for each monitoring procedure and frequency.

Principle 5: Establish Corrective Actions.

Corrective actions are defined as ***"Procedures to be followed when a deviation occurs."*** A deviation is defined as a ***"failure to meet a critical limit."*** Corrective actions are taken when monitoring shows you that a food safety hazard has gotten out of control at a CCP.

The best way to handle deviations is to have a plan of action already in place. In general, corrective action plans are used for:

1. Determining the disposition of non complying product;
2. Correcting the cause of the non-compliance to prevent a recurrence;
3. Demonstrating that the CCP is once again under control *(this means examining the process or product again at that CCP and getting results that are within the critical limits)*;

As with the monitoring procedures, specific corrective action procedures must be developed for each CCP.

Principle 6: Establish Recordkeeping Procedures.

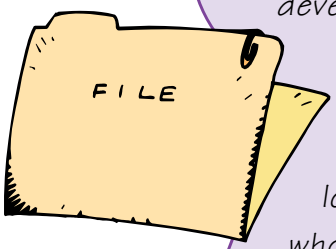
Recordkeeping procedures are important in *making* and *keeping* a HACCP system effective. Every time monitoring procedures are done, corrective actions are taken, or production equipment is serviced a detailed record of that activity is made. This continual recording of this information allows you to keep track of everything that goes on in your plant.

You can think of HACCP records in two ways, **development forms** and **day-to-day** "working" **logs**. The development forms are all of the supporting documentation that goes into building your first HACCP plan. The "working" logs are the sheets of paper where you collect the details of what happens on the production floor. You may wish to use the example forms located in Appendix A; or you may wish to create your own forms.

Generally, the records kept in the total HACCP system include the following:

- The HACCP plan itself and all supporting documentation.
- Records (including product codes) documenting the day-to-day functioning of the HACCP system such as **daily monitoring logs**, **deviation/corrective action logs**, and **verification logs**.

A Note About Recordkeeping



No matter what type of record (development or log) every record must be titled, dated and signed by the person who does the activity. In the development process this person is normally the leader of the HACCP team. For the day-to-day logs, the person would be whoever was assigned the responsibility of the procedure, such as the monitoring person.

Principle 7: Establish Verification Procedures.

Verification procedures make sure the HACCP plan is working correctly.

§ 417.4 Validation, Verification, Reassessment.

(a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.

(1) Initial validation. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

(2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:

(i) The calibration of process-monitoring instruments;

(ii) Direct observations of monitoring activities and corrective actions; and

(iii) The review of records generated and maintained in accordance with § 417.5(a)(3) of this part.

(3) Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging: finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with § 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of § 417.2 (c) of this part.

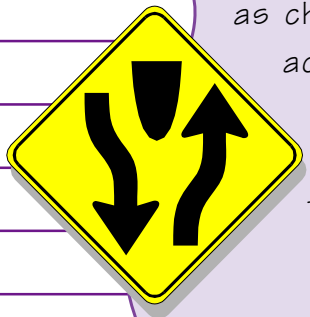
(b) *Reassessment of the hazard analysis.* Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes my include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

Notes

Verification vs. Monitoring

Verification and monitoring procedures are often confused. Monitoring is one of several sources used to verify a HACCP plan's compliance.

Recording the temperature of an oven throughout the day is a monitoring step; where as checking the accuracy of the thermometer verifies the proper functioning of the HACCP system.



Notes

A Note from the Authors -
After each section there are two "notes" pages. These pages have been set aside to help you jot-down information as you work through the manual.

Section 3

The Preliminary Steps

Review Questions are available at the end of this section.
Answers can be found in Section 5.

Introduction

Now that you have a general understanding of HACCP let's get down to the specifics. Developing a HACCP plan starts with the collection of important information. This fact-finding process is called the ***Preliminary Steps***. They are:

1. Assemble the HACCP team, including one person (consultant or employee) who is HACCP trained.

2. Describe the product and its distribution.

3. Develop a complete list of ingredients and raw materials.

4. Develop a flow diagram that completely describes your process.

5. Verify the flow diagram.

A Note from the Authors:
In order to show you how a HACCP plan is put together, we are going to show you examples of filled-out HACCP development forms (see sections 3 & 4.) The thought of filling out all these forms can be a bit overwhelming at first, however, it is a straightforward process. We are going to be using an "Example Plant" to show you what each one of these forms might look like when completed. Here is some background information on our "Example Plant."

- *Their product is beef jerky.*
- *They have been in business for over 30 years and are in their third generation of family ownership.*
- *They sell their jerky at retail through local farmer's markets and wholesale to vendors.*

Step 1: Assemble the HACCP Team

Your first task in developing a HACCP plan is to assemble your HACCP team. The HACCP team consists of individual(s) who will gather the necessary information for your HACCP plan. The HACCP team needs to be aware of the following:

- Your product/process
- Any food safety programs you already have
- Food safety hazards of concern
- The seven principles of HACCP

In a very small plant, perhaps only one individual is available to be on the HACCP team. This is perfectly acceptable; however, you can get help from as many people as you need to make the team function effectively.

The HACCP team will begin by collecting scientific data. Remember, the team isn't limited to internal resources. If needed, outside expertise is available through state extension offices, trade or professional associations, consultants, universities and libraries.

However you decide to approach it, your HACCP team is ultimately responsible for building your HACCP plan.

The First Meeting

Who should be there, and what should we do? Here's a sample agenda...

Remember, it only takes one person to make a HACCP team!

- First, describe your product - what it is, and where it's going.
- Next, gather a complete list of ingredients.
- Think about who will be eating the food. Will it go to schools? Hospitals? Other institutions? Remember that small children, the elderly, and people with weakened immune systems are much more likely to die from unsafe foods than other people!

Working with the "HACCP Team" Form

The Example Plant has six HACCP team members. One of whom is not only the general manager, but is also the owner. It is important to list all the team members and to state clearly what their HACCP team role is. *(As you might think, filling out this first form is relatively simple.)* Don't forget to **sign and date the form**.

[A note about the forms. As with all HACCP forms and logs, the person who is responsible for an activity (whether it be drafting the forms, or doing the monitoring) should be the one who signs and dates the form or log.]

Step 1

HACCP Team Form

Team Members	Role
Cindy Jones	General Manager
Mary Weston	Quality Control
Mark Baker	Wet Room Supervisor
Susan Smith	Packing Supervisor
Joe Jones	Extension Service
Pam Smith	Local Microbiologist

Developed by: Cindy Jones **Date:** 12/10/98

Step 2: Product/Process Description

Next, make a complete description of the ingredients, and the processing methods and distribution for your product. You can think of this step as a general overview of your product/processes. It is a way of getting "the big picture" about your product. Don't get bogged down; start with just one product or process. Section 417.2(b)(1) of the regulations lists nine product categories into which meat and poultry production can be grouped; they are shown below.

- Slaughter - all amenable species
- Raw product - ground
- Raw product - not ground
- Thermally processed - commercially sterile
- Not heat treated - shelf stable
- Heat treated - shelf stable
- Fully cooked - not shelf stable
- Heat treated but not fully cooked - not shelf stable
- Product with secondary inhibitors - not shelf stable

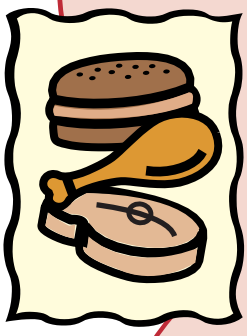
One way to cut down on the paperwork that is a part of HACCP system development is to control all your processes that are in the same process category using a single HACCP plan. **This is especially advantageous for very small establishments which may produce many different products.** If those products differ only in characteristics that would not affect safety, e.g. the diameter of the casings into which the emulsion is stuffed, they are clearly in the same process category and may be covered by the same HACCP plan.

Generic HACCP Models

FSIS has developed generic HACCP models for the processes listed above and two more specific processes, Mechanically Separated Species/Deboned Poultry and Irradiation (including all forms of approved irradiation procedures.) You are encouraged to order these free modules as guides to assist you in customizing it to fit your particular plant, its products, processes and plant layouts. For ordering information see page 10.

Nine Product Categories

The HACCP Regulation defines the following processing categories:



- Slaughter - all amenable species
- Raw product - ground
- Raw product - not ground
- Thermally processed - commercially sterile
- Not heat treated - shelf stable
- Heat treated - shelf stable
- Fully cooked - not shelf stable
- Heat treated but not fully cooked - not shelf stable
- Product with secondary inhibitors - not shelf stable

Working with the "Product/Process Description" Form

Describe your product as completely as you can by answering the questions on the form. Add any other important information. The Example Plant kept their descriptions brief, but specific.

Common name? *(A common name for the product)* For example, a cooked sausage could be called franks, hot dogs or wieners.

How will this product be used? *(How is the product prepared and eaten?)* Categories include: Ready-to-eat, heated prior to consumption, or sent out for further processing.

The type of package? *(What is it made of, what is special about it?)* Categories might include: bulk packaged (e.g. plastic bag, vacuum packaged), layer or stack packed, or patty packed.

Length of shelf life? At what temperature? *(What is the "sell by" date? Does temperature affect shelf life?)* Does it need to be refrigerated?

Where will it be sold? *(Who is the intended consumer?)* Will it be sold wholesale or retail? If your product is purchased for use in hospitals, schools or institutions, you may need stricter distribution controls.

Labeling instructions? *(What does the consumer need to know about the product?)* Instructions can include: "Keep refrigerated" or "keep frozen" and "cook thoroughly."

Is special distribution control needed? *(Does the product need specific care?)* Will the product become unsafe if not taken care of properly in transit? Raw product being shipped to the grocer needs to be kept refrigerated or frozen.

Sign and date the form.

Step 2

Product/Process Description Form

1. Common Name?

Beef Jerky

2. How will this product be used?

Ready-to-eat

3. Type of package?

Vacuum Pack Plastic bags, assorted sizes

4. Length of shelf life? at what temperature?

Room temperature - 6 months

5. Where will be sold?

Retail, Wholesale (East Coast)
No "At Risk" groups identified as consumers

6. Labeling instructions?

(None)

7. Is special distribution control needed?

No. Shelf Stable, vacuum sealed.

Developed by: Cindy Jones **Date:** 12/10/98

Step 3: Develop a List of Ingredients

The third task for the HACCP team is to develop a list of ingredients and raw materials for each product/ process. The HACCP team needs to list everything that goes into your product. This includes packaging materials used.

To begin, you may want to divide your ingredients into two main categories:

- Meat or poultry such as boneless beef or chicken parts with skin.
- Other ingredients such as spices and preservatives.

After that, you can break down these categories into an even more specific list as shown on the Ingredients and Raw Materials Form.

Working with the "Ingredients and Raw Materials" Form

As you can see the Example Plant's ingredients and materials fall into several categories. If the category does not apply to your product/process you don't need to write anything in that space.

[If you use pre-packaged or pre-blended ingredients such a seasoning mix you can list it by blend (mix) name and just staple that product's information to the back of your Product/Ingredient form.]

Sign and date the form.

Step 3
Ingredients & Raw Materials Form

Product/Process Category: Heat Treated, Shelf Stable

Product/Examples: Beef Jerky

Meat/Poultry and Byproducts	Nonmeat Food Ingredients	Binders/ Extenders
Eye rounds - Beef		
Spices/ Flavorings	**Restricted Ingredients**	**Preservatives/ Acidifiers**
Garlic Pepper (Black) Soy Sauce		Soy Sauce
Liquid	**Packaging Materials**	**Other**
Tap water	Vacuum Plastic pouch Assorted Labels	

Developed by: Cindy Jones **Date:** 12/10/98

Step 4 & 5 – Develop and Verify a Flow Diagram

At steps 4 and 5 the team will create a document that will be used over and over again in the HACCP plan development process. The HACCP team needs to look closely at the production process and make a flow diagram that shows all the steps used to prepare the product. You don't need to include steps that are not directly under your control, such as distribution. Another way to organize the flow diagram is to track your product according to the ingredient categories from step 3.

The flow diagram doesn't need to be complex. Looking at your plant's floor plan can help you visualize the process from receiving to shipping. To find all the food safety hazards in your process you need to know exactly what steps that product/process goes through.

After the HACCP team has completed the flow diagram, it needs to be checked for accuracy. To do this, walk-through the plant to make sure that the steps listed on the diagram realistically describe what occurs during the production process. If possible, have someone who didn't make the flow diagram do the "walk-through."

Working with the "Flow Diagram Development and Verification" Form

The Example Plant divided their flow diagram into three paths. Each of these paths represents one or more ingredients and raw materials. It made sense to combine certain categories. They grouped all meat items into "Meat"; all non-meat food ingredients such as spices and preservatives into "Other Ingredients"; which just left "Packaging Materials." These three categories represent the three main process routes that occur in their plant.

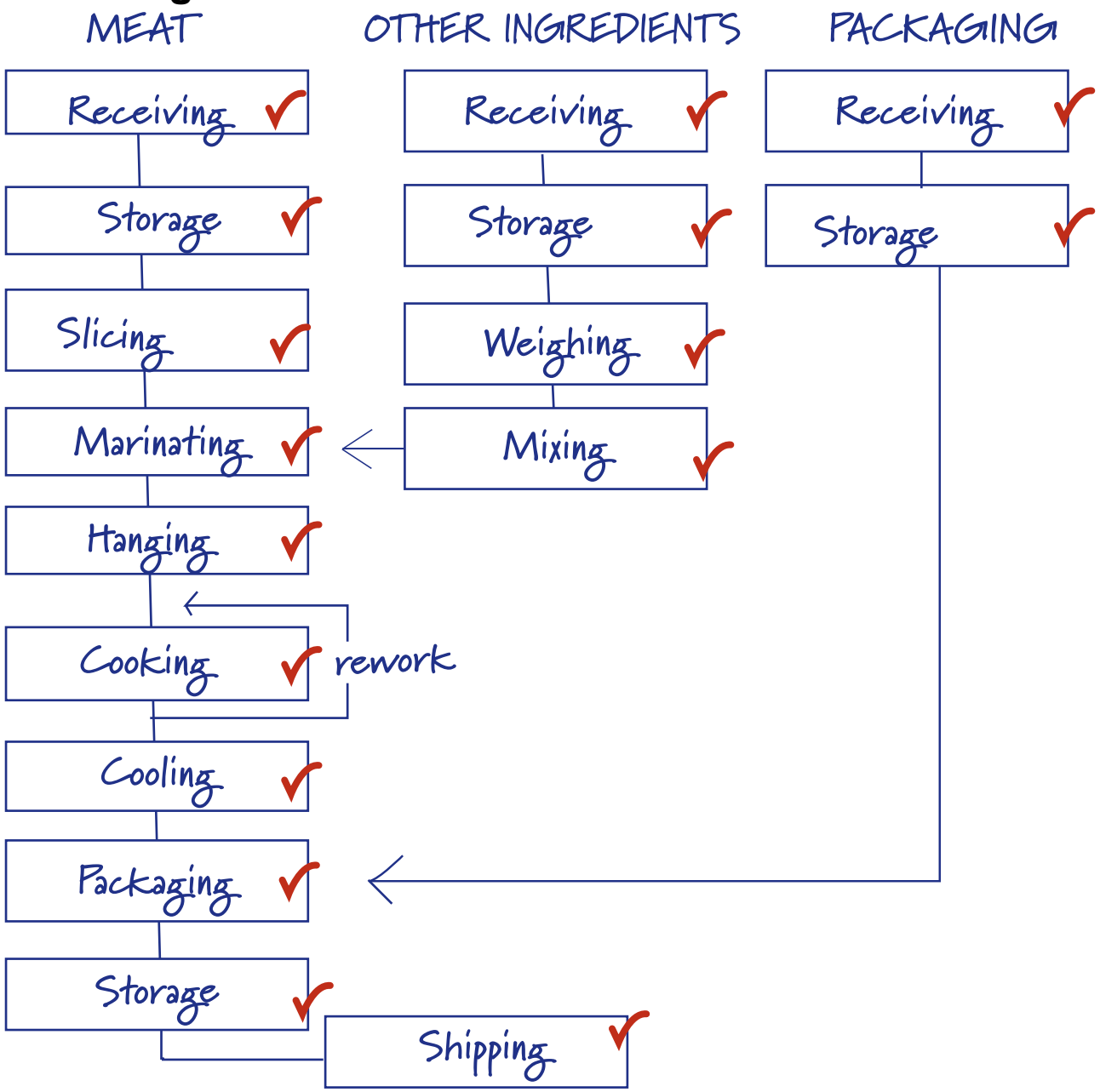
After the HACCP team completed their drawing, the flow diagram was **checked, signed and dated**. In the Example Plant as each step was verified they placed a red check mark. The form must be **signed and dated** again after it is checked/reviewed.

Steps 4 & 5

Flow Diagram Development & Verification Form

Product/Process Name: Beef Jerky

Flow Diagram:



Developed by: Cindy Jones **Date:** 12/10/98

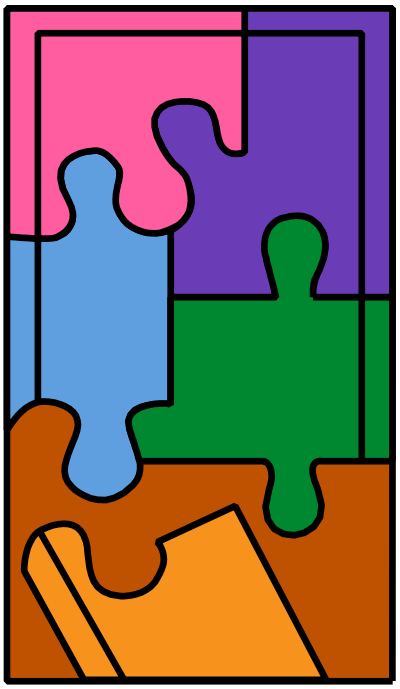
Verified by: Mary Weston **Date:** 12/12/98

Conclusion

The Example Plant has successfully completed the fact-finding part of the HACCP development process. Your work through the preliminary steps should have produced two tangible pieces of information…

1. A comprehensive list of ingredients and raw materials, and

2. A step-by-step production process breakdown, laid out simply in a flow diagram.



With this information you are now ready to proceed to the next stage: **Utilizing the 7 Principles of HACCP**.

Question & Answer

Don't forget that "Notes" pages,
and "Review Questions"
have been provided to help you
better understand the
HACCP development steps...

Notes

Notes

Review Questions

[The answers to these Review Questions are in Section 5.]

1. When describing your product, which of the following questions should you ask:

a.) What is the type of packaging?
b.) Where will it be sold?
c.) Is special distribution control needed?
d.) All of the above.

2. After the team has completed the flow diagram, you need to:

a.) Conduct a hazard analysis.
b.) Describe your product.
c.) Verify its accuracy.

3. Your HACCP team is:

a.) Ultimately responsible for building your HACCP plan.
b.) Responsible for passing HACCP information on to others involved in the production process.
c.) A and B.

4. When you've finished all of the preliminary steps:

a.) You will have gathered all of the information you'll need to build a HACCP plan.
b.) You are ready to create your flow diagram.

5. What should you do after answering all the questions on the product description form?

a.) Sign the form.
b.) Date the form.
c.) Sign and date the form.
d.) None of the above.

6. Often, in very small plants:

a.) HACCP is unnecessary.
b.) A flow diagram is unnecessary.
c.) Only one or two individuals are available to act as the HACCP team.
d.) B and C.

7. The flow diagram:

a.) Should include as much information as possible regarding the product.
b.) Should contain supporting information.
c.) Should be as simple as possible but show all process steps.

Section 4

Utilizing the 7 Principles of HACCP

Review Questions are available at the end of this section.
Answers can be found in Section 5.

This section is about using the seven principles of HACCP to make HACCP work for you! The first part you just finished. That's where you gathered all the specific information about your plant's product and process. The second part is where you put that information to use. When you finish these next seven principles you'll have in your hands a *complete* HACCP plan.

Understanding Hazards & Controls

Before we start with the first principle we need to quickly review two important ideas: "*Food Safety Hazards*" and "*Preventive Measures.*" Food Safety Hazards, as defined in the Regulation 9 CFR 417.1 ***"Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption."*** There are three types of hazards: biological, chemical, and physical; the most common food safety hazards are biological. More than 95% of all human foodborne illnesses from meat or poultry are caused by bacteria.

[The tables below list many of the most common hazards and their associated preventive measures. You should take a moment to look over this useful resource.]

TABLE 1
Characteristics of Growth
for Nine Pathogens Associated with Meat and Poultry Products

Pathogens	Temperature for Growth	pH	Minimum A_w
Bacillus cereus	5 - 48°C	4.9 - 9.3	0.912
Campylobacter jejuni	30 - 47°C	4.9 - 7.5	---
Clostridium botulinum (Types A, B, E)	3.3 - 46°C	>4.6	0.94
Clostridium perfringens	15 - 50°C	5.0 - 8.3	0.95
***Escherichia coli* O157:H7**	10 - 44.5°C	4.5 - 9.0	---
Listeria monocytogenes	1.0 - 45°C	4.4 - 9.6	0.90
Salmonella	5 - 46°C	4 - 9	0.94
Staphylococcus aureus	6.5 - 46°C	4.5 - 9.3	0.83
Yersinia enterocolitica	0 - 45°C	4.2 - 9.6	0.94

TABLE 2
Types of Chemical Hazards

Location	Hazard
Raw Materials	Pesticides, antibiotics, hormones, toxins, fertilizers, fungicides, heavy metals, PCBs.
	Color additives, inks, indirect additives, packaging materials.
Processing	Direct food additives - preservatives (high levels of nitrites), flavor enhancers, color additives.
	Indirect food additives - boiler water additives, peeling aids, defoaming agents.
Building and Equipment Maintenance	Lubricants, paints, coatings.
Sanitation	Pesticides, cleaners, sanitizers.
Storage and Shipping	All types of chemicals.

TABLE 3
Examples of Physical Hazards

Cause	Source
Glass	Bottles, jars, light fixtures, utensils, gauge covers, thermometers.
Metal	Nuts, bolts, screws, steel wool, wire, meat hooks.
Stones	Raw materials.
Plastics	Packaging materials, raw materials.
Bone	Raw materials, improper plant processing.
Bullet/BB Shot/Needles	Animals shot in field, hypodermic needles used for injections.
Jewelry	Pens/pencils, buttons.

Preventive Measures are defined as "***Physical, chemical, or other means that can be used to control an identified food safety hazard.***"

TABLE 4
Examples of Preventive Measures for Biological Hazards

Pathogen	Preventive Measure or Control
Bacillus cereus	**Proper holding and cooling temperatures of foods; thermal processing of shelf-stable canned food.**
Campylobacter jejuni	**Proper pasteurization or cooking; avoiding cross-contamination of utensils, equipment; freezing; atmospheric packaging.**
Clostridium botulinum	**Thermal processing of shelf-stable canned food; addition of nitrate and salt to cured processed meats; refrigeration of perishable vacuum packaged meats; acidification below pH 4.6; reduction of moisture below water activity of 0.93.**
Clostridium perfringens	**Proper holding and cooling temperatures of foods; proper cooking times and temperatures; adequate cooking and avoidance of cross-contamination by unsanitary equipment.**
Listeria monocytogenes	**Proper heat treatments; rigid environmental sanitation program; separation of raw and ready-to-eat production areas and product.**
***Salmonella* spp.**	**Proper heat treatment; separation of raw and cooked product; proper employee hygiene; fermentation controls; decreased water activity; withdrawing feed from animals before slaughter; avoiding exterior of hide from contacting carcass during skinning; antimicrobial rinses; scalding procedures; disinfecting knives.**
Staphylococcus aureus	**Employee hygiene; proper fermentation and pH control; proper heat treatment and post-process product handling practices; reduced water activity.**
Yersinia enterocolitica	**Proper refrigeration; heat treatments; control of salt and acidity; prevention of cross-contamination.**

TABLE 5
Examples of Preventive Measures for Chemical Hazards

Hazard	Preventive Measure
Naturally-Occurring Substances	Supplier warranty or guarantee; verification program to test each supplier's compliance with the warranty or guarantee.
Added Hazardous Chemicals	Detailed specifications for each raw material and ingredient; warranty or letter of guarantee from the supplier; visiting suppliers; requirement that supplier operates with a HACCP plan; testing program to verify that carcasses do not have residues.
In-Process Chemicals	Identify and list all direct and indirect food additives and color additives; check that each chemical is approved; check that each chemical is properly used; record the use of any restricted ingredients.

TABLE 6
Examples of Preventive Measures for Physical Hazards

Hazard	Preventive Measure
Foreign objects in raw materials	Supplier's HACCP plan; use of specifications, letters of guarantee; vendor inspections and certification; in-line magnets; screens, traps, and filters; in-house inspections of raw materials.
Foreign objects in packaging materials, cleaning compounds, etc.	Supplier's HACCP plan; use of specifications, letters of guarantee; vendor inspections and certification; in-house inspections of materials.
Foreign objects introduced by processing operations or employee practices	In-line metal detectors; visual product examinations; proper maintenance of equipment; frequent equipment inspections.

You should now be able to identify many types of hazards. You should also know where to begin looking for their preventive measures. This investigative skill is one that you'll get plenty of practice.

Principle 1: Conduct a Hazard Analysis

Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur and describe the preventive measures.

A thorough hazard analysis is one of the keys to building an effective HACCP plan. The hazard analysis process involves identifying hazards that are reasonably likely to occur in the absence of control and their preventive measures. In the first "Identification" stage, the HACCP team identifies and lists food safety hazards that may be introduced or increased at each step in the production process.

Then, in the second "Evaluation" stage, each food safety hazard is evaluated based on how likely it is to occur. The term "***reasonably likely to occur***" is the ruler against which each hazard can be measured. Also during this evaluation stage the HACCP team investigates the appropriate preventive measures that will control the "likely to occur" food safety hazards.

[Hazards can vary greatly from one plant to another due to differences in sources of ingredients, product formulations, processing equipment, processing methods, duration of the processes, and storage methods. Make sure that your hazard analysis takes into account what's unique about your establishment.]

Preventive Measures

When determining the appropriate preventive measures for an existing food safety hazard, keep in mind the wealth of regulatory, scientific, and historical support. Over the years, both industry and regulators have done a lot of work in identifying food safety hazards and preventive measures that can be used to control them in food production. Don't think that you have to go it alone in this search.

[If you have a question about a specific food safety hazard you can call the FSIS Technical Support Hotline 1-800-233-3935, ext. 2 and they'll help you.]

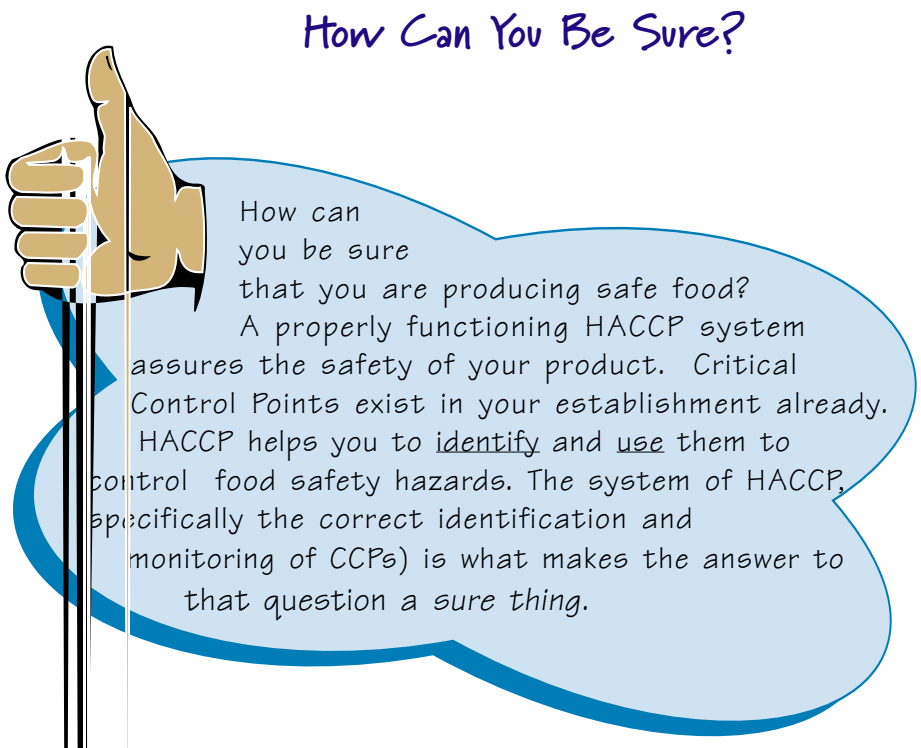
Hazard Identification & Evaluation

The following steps can help you and the HACCP team get started conducting your hazard analysis:

First, look back over the **product description** and look for information that could impact your hazard analysis. For example, if consumers who are at a high risk for illness (i.e. people in schools or hospitals) will use your product, then you may need to look at certain biological hazards in your process more closely. What may be acceptable levels for the average consumer may be too high for these other groups. This fact could affect the preventive measures you choose for your process.

Here are some questions you can ask yourself to better understand the hazard identification process:

- Have the animals going to slaughter been given any hazardous chemicals?
- Are additives or preservatives added to the product to kill or inhibit the growth of bacteria?
- Will the amount of acidic ingredients affect the growth/ survival of bacteria?
- Does the product need to be refrigerated/frozen or kept dry in storage or during transit?



Second, look at the **product ingredients** and **packaging materials** that you listed earlier. In order to find all of the food safety hazards that are reasonably likely to occur, you need to know detailed characteristics about all the ingredients used in your process, as well as possible ingredient interactions.

Here are some questions you can ask about the ingredients:

- Could these ingredients or packaging materials contain any pathogenic bacteria, dangerous chemicals, or harmful physical objects?
- If contaminated or mishandled, could the ingredients or materials support the growth of pathogenic bacteria?
- Are hazardous chemicals used in growing, harvesting, processing or packaging an ingredient?
- Is this ingredient hazardous if used in excessive amounts?

Third, determine if any food safety hazards exist for each processing step listed in the **process flow diagram**.

Here are some questions you can ask for each production step:

- Could contaminants reach the product during this processing step?
- Could this step create a situation where an ingredient, work in process, or finished product becomes contaminated with pathogens?
- Could this step introduce a chemical or physical hazard into the product?
  Possibilities for the three questions above include: worker handling, contaminated equipment or materials, cross-contamination from raw materials, leaking valves or pipes, splashing, etc.
- Could bacteria multiply during this process step to the point where they became a hazard?
  Consider product temperature, hold time, etc.

Keep Good Notes

A summary of the HACCP team meetings and the reasons for each decision during the hazard analysis should be kept for future reference. These documents will be a great help to you when you have to review and update your hazard analysis and HACCP plan.

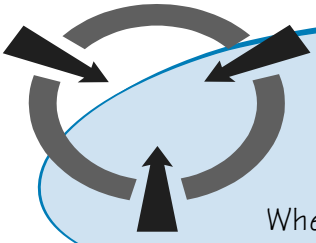
Finding Preventive Measures

Now that you have a good idea of what you're looking for in the way of hazards you can flip back to the example tables of preventive measures on pages 44-47 to find out some ways to keep those hazards under control.

Preventive Measures

It's sometimes the case that more than one preventive measure may be required to control a specific hazard, or that more than one hazard may be controlled by one preventive measure. As you go through the hazard analysis, you may recognize preventive measures already in place in your production process. The key to a successful hazard analysis is to link these measures to the food safety hazards you have just identified.

Here's a Tip



When sitting down to figure out which steps in your process might or might not be CCPs, a common pitfall is to name too many.

Working with the "Hazard Analysis" Form

To explain how this form works we are going to show you three steps for which the Example Plant did a hazard analysis. The form is structured so that the three food safety hazard categories (biological, chemical, and physical) are addressed in each of the four questions. Don't forget that you need to fill out the top of the form with the appropriate information, such as the product/process name, and the process steps from the flow diagram. You also need to **sign and date the form** when it's complete.

The first production step we're going to look at is receiving meat.

- For the first question all you need to do is state what food safety hazards are present at that step. *The Example Plant listed pesticides, hormones, and antibiotics as a chemical hazard. They listed pathogenic bacteria as a biological hazard because bacteria is found on all raw meat. They also listed plastic and bone fragments as physical hazards because the meat comes to them in plastic sheaths, bone fragments, buckshot and needles are possible in meat products.*

- The second question asks you to decide whether or not that hazard is reasonably likely to occur at that step. *The Example Plant answered "No" for the chemical, "Yes" for the biological, and "No" for the Physical.*

- The third question is where you explain **why** you answered "*Yes*" or "*No,*" to the question of "*reasonably likely to occur.*" *For the chemical hazard, the Example Plant's justification is that these sources are normally within defined limits. For the biological hazard they assume that the bacteria is on the meat prior to arrival, so that it continues to be a potential hazard. They said "No" to both the plastic and bone fragments because in both cases there has never historically been a problem with these types of physical hazards in their plant.*

[This "historical" basis for deciding whether a food safety hazard is "reasonably likely to occur" is perfectly legitimate. If your plant has a clean track record regarding a particular hazard, it's fine to include that information in your HACCP plan. All information must be documented.]

- The final question on the hazard analysis form is the place where you write the specific preventive measure(s) that will control the hazard you said was likely to occur. *With each shipment of meat the Example Plant receives they feel that the "Letter of Guarantee" from their supplier reasonably assures them the meat has been kept at a temperature adequate to control bacterial growth. However, just because they have one preventive measure hasn't stopped them from also having a second preventive measure. They also physically check the condition and temperature of the truck and meat products, to make sure everything meets their standards.*

HACCP Principle 1

Hazard Analysis Form

Product/Process Name: Beef Jerky

Process Step from Flow Diagram: Receiving Meat

Food Safety Hazard Analysis -

C: Chemical,	B: Biological,	P: Physical:
List the Hazards: Pesticides, Hormones, Antibiotics	Pathogens	Plastic, Bone Fragments
Is the Hazard *Reasonably Likely to Occur*? Yes / No No	Yes	No
What is the Basis for your Decision? No evidence of any historical occurrence at this plant.	Loss of control in Time/ Temp or moisture level can promote harmful bacterial growth	No evidence of any historical occurrence at this plant from this product/source.
What Preventive Measures can be applied at this step to *Prevent*, *Eliminate*, or *Reduce* the hazard to an acceptable level?	Collect "Letter of Guarantee" from supplier that stipulates your requirements. If exceeds limits, product won't be accepted from supplier.	

Developed by: Cindy Jones **Date:** 12/13/98

The second production step we're going to look at is cooking.

List the hazards.

The Example Plant listed a chemical hazard of sanitizing chemicals because it's possible that traces of these substances could be on the equipment from the last time it was cleaned. They also listed a biological hazard because bacteria is unavoidable on all raw meat.

[If you don't find a particular type of hazard at a step it's okay to write "None Identified" as the Example Plant did.]

Is it "reasonably likely to occur"?

They answered "No" for the chemical hazard, and "Yes" for the biological hazard.

What is the basis for your decision?

The Example Plant decided the sanitizing chemicals wouldn't be a hazard likely to occur because their proper use is thoroughly covered by existing SSOPs. They decided "Yes" for the biological hazard for the same reason as in the preceding process step. [When working on your HACCP plan, you might want to revisit your SSOP's.

What are the preventive measures?

The Example Plant identified two preventive measures, cooking and water activity reduction for the biological hazard. They said this because the cooking and the water activity reduction will help to reduce the hazard.

HACCP Principle 1

Hazard Analysis Form

Product/Process Name: Beef Jerky

Process Step from Flow Diagram: Cooking

Food Safety Hazard Analysis -

C: Chemical,	B: Biological,	P: Physical:
List the Hazards: Residual Sanitizing Chemicals	Pathogen survival and growth in finished product	(None Identified)
Is the Hazard *Reasonably Likely to Occur*? Yes / No No	Yes	(None Identified)
What is the Basis for your Decision? SSOP addresses this issue.	Loss of control in Time/ Temp or moisture level can promote harmful bacterial growth	(None Identified)
What Preventive Measures can be applied at this step to *Prevent*, *Eliminate*, or *Reduce* the hazard to an acceptable level?	Smokehouse temperature is 190°F	

Developed by: Cindy Jones **Date:** 12/13/98

The third production step we're going to look at is cooling.

List the hazards.

They listed the biological hazard of cross-contamination because any time when you have raw and finished product in the same plant the possibility for the raw product to cross-contaminate the finished product exists. The Example Plant also listed plastic as a physical hazard because this is the step where they "Pull" the jerky strips off of the cooking trees into large plastic barrels.

Is it "reasonably likely to occur"?

They answered, "No" for the biological, and "No" for the physical.

What is the basis for your decision?

The Example Plant said that the biological hazard was not likely to occur because the raw and cooked products are strictly kept apart as called for in their SSOPs, Also the water activity in the finished product is too low for bacteria to significantly grow. They said "No" to the physical hazard because the plastic barrels that are used are made of an extremely sturdy type of plastic and there's never historically been a problem with plastic shavings at this plant getting into the jerky.

What are the preventive measures?

[There aren't any preventive measures listed here because no food safety hazards were found to be reasonably likely to occur.]

HACCP Principle 1

Hazard Analysis Form

Product/Process Name: Beef Jerky

Process Step from Flow Diagram: Cooling

Food Safety Hazard Analysis -

C: Chemical,	B: Biological,	P: Physical:
List the Hazards:		
(None Identified)	Pathogen cross-contamination	Plastic
Is the Hazard *Reasonably Likely to Occur*? Yes / No		
(None Identified)	No	No
What is the Basis for your Decision?		
(None Identified)	The Water Activity is too low for significant bacterial growth.	No evidence of any historical occurrence at this plant.
What Preventive Measures can be applied at this step to *Prevent*, *Eliminate*, or *Reduce* the hazard to an acceptable level?		

Developed by: Cindy Jones **Date:** 12/13/98

Principle 2: Identify Critical Control Points

Identify the Critical Control Points (CCPs) in the process.

A critical control point is defined as ***"A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels."*** Everything in your HACCP plan revolves around the proper identification of CCPs.

How does a step in your production process become a CCP? Before it can be a critical control point, it must be found to be a **control point**. Control points are steps in your process where you have identified a food safety hazard.

Some of the most common CCPs are:

- Chilling or freezing to a specified temperature to prevent bacteria from growing.
- Cooking that must occur for a specific time and temperature in order to destroy bacteria.
- Prevention of cross contamination between raw and cooked product.
- Certain processing procedures, such as filling and sealing cans, mixing and spicing, etc.
- Certain slaughter procedures.

These are just a few examples of possible CCPs. Different plants, preparing the same food, can identify different food safety hazards and different critical control points. Usually no two plants have the same floor plan, equipment, or ingredients. The CCPs you identify will reflect the uniqueness of your processing plant.

One of the tools used to help determine critical control points is a **"CCP Decision Tree."** The use of a Decision Tree to identify significant hazards is not necessary for you to meet regulatory requirements. However, the thought process may be helpful for your team; you want to make sure that your HACCP system meets regulatory requirements.

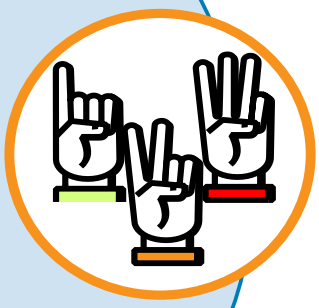
Numbering Your CCP's

Once you've been through your entire production process and have successfully identified all the CCPs, there's one more thing you need to do to get that CCP set up. You need to organize them. Feel free to do this any way that works for your business.

One easy way to accomplish this is to develop a simple numbering system.

It's a good idea to always write "CCP" before the numbers - this can make your documents easier to understand. For instance you could write it like: CCP#1, CCP#2, CCP#3.

Also, remember that you could have more than one CCP (for a designated food safety hazard) at a given process step or one CCP may control more than one process step, or one CCP may control more than one hazard. In this case you might want to include the letter "B", "C", or "P" to identify whether it is a biological, chemical, or physical hazard. For example: CCP#1B, CCP#1C, CCP#2P, CCP#2C.



[Whether you use this tool or another one, you need to apply the same thought to each step in the process where you have identified a food safety hazard.]

Working with the "CCP Decision Tree" Form

The Example Plant used the CCP Decision Tree to take a closer look at both of the steps in their process where they determined food safety hazards were reasonably likely to occur. [*Go ahead and read the four questions on the form and then we'll look at each one in detail. Again, this approach is not necessary to meet regulatory requirements.*]

The first step they looked at was receiving meat.

Question 1a.

The Example Plant answered "Yes" because the "Letter of Guarantee" from the supplier, and checking the temperature of the truck and products are the preventive measures for this biological hazard.

Question 1b.

If you answered "Yes" for question 1a, then you don't need to worry about question 1b. (If you haven't yet identified a preventive measure for a food safety hazard, question 1b will not let you move down the CCP Decision Tree until you do.)

Question 2.

(This question asks whether or not this step "*prevents, eliminates, or reduces*" to acceptable levels, the food safety hazard you are working with.) *The Example Plant said "No" because simply receiving the meat doesn't mean the hazard is controlled.*

Question 3.

The Example Plant said "Yes" here because, if not controlled, the biological hazard could get worse.

Question 4.

(Here the HACCP team must decide if this step is the last point at which control could be applied to the hazard.) *In this case the Example Plant found that, in fact, a later step (i.e. cooking) could control this biological food safety hazard. Thus this process step was* ***not a CCP****.*

Critical Control Point Decision Tree
for the production of cooked products

Process/Step: Receiving Meat

Question 1a

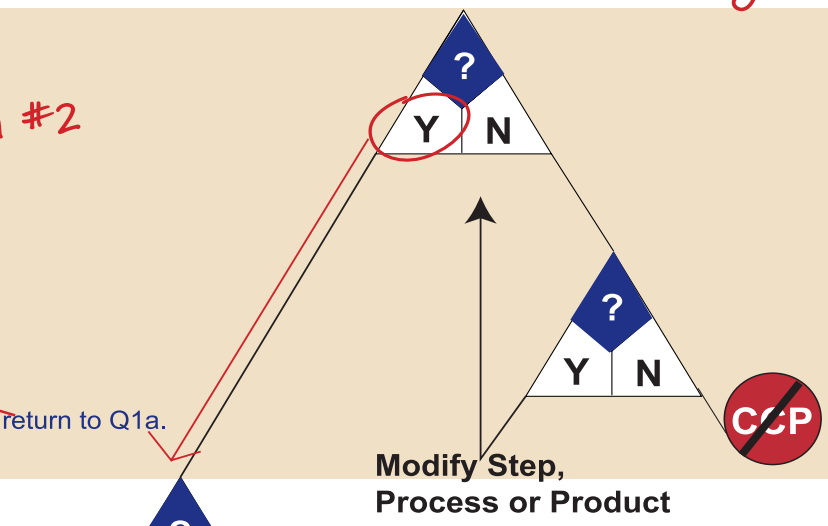
Do preventive measures exist for the identified hazard(s)? Yes, go Question #2

If no - go to Q1b.
If yes - go to Q2.

Question 1b

Is control at this step necessary for safety?

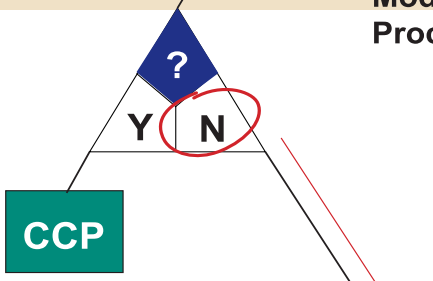
If no - not a CCP
If yes - modify step, process or product and return to Q1a.



Question 2

Does this step eliminate or reduce the likely occurence of a hazard(s) to an acceptable level? No

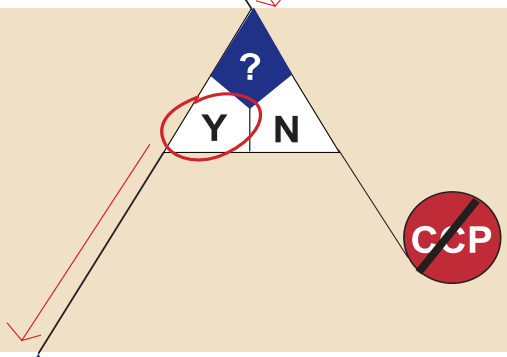
If no - go to Q3.
If yes - CCP.



Question 3

Could contamination with identified hazard(s) occur in excess of acceptable levels or could these increase to unacceptable levels? Yes

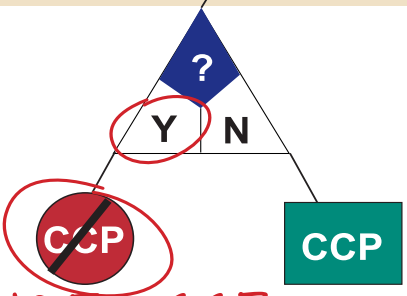
If no - not a CCP.
If yes - go to Q4.



Question 4

Will a subsequent step eliminate the identified hazards or reduce the likely occurence to an acceptable level?

If no - CCP.
If yes - not a CCP.



RESULTS: Yes – so it's NOT a CCP

BIOLOGICAL	CHEMICAL	PHYSICAL
☐ CCP # ____	☐ CCP # ____	☐ CCP # ____
☒ Not a CCP	☐ Not a CCP	☐ Not a CCP

Developed by: Cindy Jones **Date:** 12/13/98

The second step they looked at was cooking.

Question 1a.

The Example Plant answered "Yes" here because they had identified the preventive measure of cooking (i.e. time and temperature) for this step.

Question 1b.

As in the receiving example, move on to question 2.

Question 2.

*The Example Plant said that "Yes" cooking would eliminate the hazard at this step. They stopped here at question 2 because they reached a positive result...**their CCP**. Thus, there wasn't any need to go on to questions 3 and 4.*

FSIS Technical Hotline

Don't know what to do, or what direction to go in? The Technical Support Hotline can help. Call 1-800-233-3935, ext. 2 and they can direct you to the rules and regulations that apply to your question.

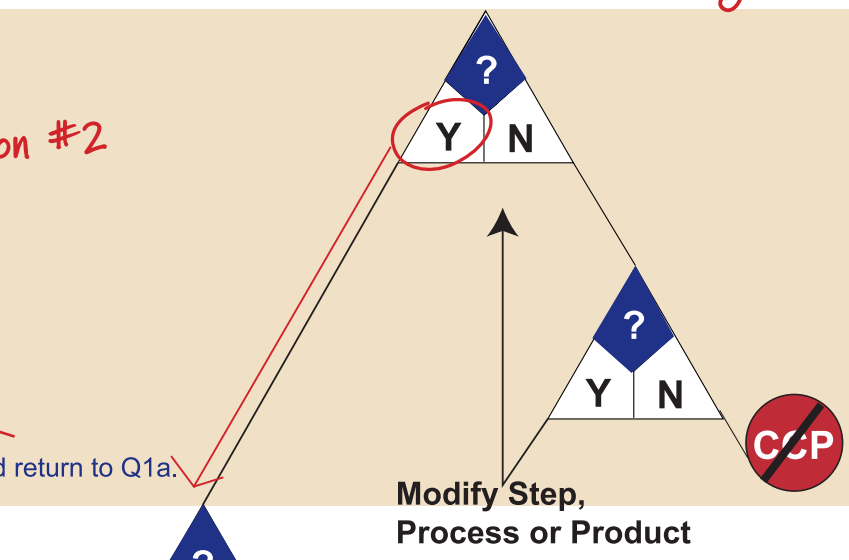
[After finding all the CCPs in your process, the HACCP team needs to organize them. At the bottom of the CCP Decision Tree Form the Example Plant named the cooking CCP "CCP#01B". The "01" tells them what number the CCP is, and the "B" tells them whether it is a biological, chemical, or physical food safety hazard.]

Critical Control Point Decision Tree
for the production of cooked products

Process/Step: Cooking

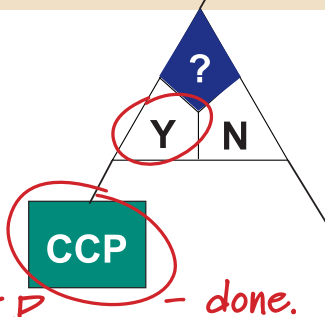
Question 1a
Do preventive measures exist for the identified hazard(s)? Yes, go Question #2
- If no - go to Q1b.
- If yes - go to Q2.

Question 1b
Is control at this step necessary for safety?
- If no - not a CCP
- If yes - modify step, process or product and return to Q1a.

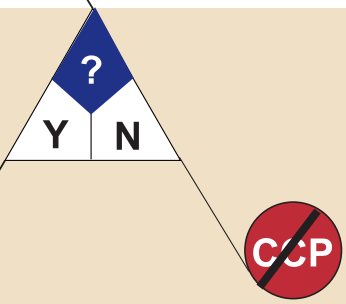


Question 2
Does this step eliminate or reduce the likely occurence of a hazard(s) to an acceptable level? Yes
- If no - go to Q3.
- If yes - CCP.

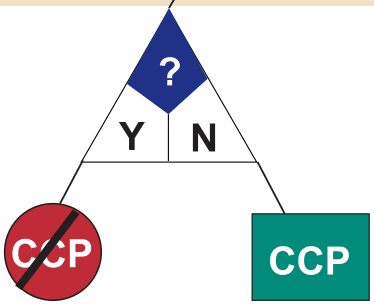
Identified as CCP - done.



Question 3
Could contamination with identified hazard(s) occur in excess of acceptable levels or could these increase to unacceptable levels?
- If no - not a CCP.
- If yes - go to Q4.



Question 4
Will a subsequent step eliminate the identified hazards or reduce the likely occurence to an acceptable level?
- If no - CCP.
- If yes - not a CCP.



RESULTS:

BIOLOGICAL	CHEMICAL	PHYSICAL
☒ CCP # #01B	☐ CCP # ____	☐ CCP # ____
☐ Not a CCP	☐ Not a CCP	☐ Not a CCP

Developed by: Cindy Jones **Date:** 12/13/98

Principle 3: Establish Critical Limits for Each Critical Control Point

Establish critical limits for preventive measures associated with each identified CCP.

A critical limit is defined as "***The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.***" You can think of a critical limit as a *boundary of safety* for a CCP. The critical limit is the numerical value that **must** be reached to assure that hazards have been controlled. An example would be that "all poultry must be chilled immediately after processing to a temperature of 40ºF or less 9 CFR 381.66(b.)

Each CCP will have at least one (possibly more) preventive measures that need to be controlled to assure this prevention, elimination or reduction of food safety hazards. To be effective, each critical limit should be:

- **Based on proven factual information.**
  A few ways that information and recommendations for appropriate limits can be obtained are: from regulatory requirements, scientific literature, and consultation with experts. If regulatory requirements exist they must be met or exceeded.

- **Objectives are measurable or observable, such as time and temperature.**

- **Appropriate and reasonable for the food product and operation.**
  You should consider the type of equipment, the volume of product being produced, how the critical limit will be monitored and frequency of monitoring.

- **Specific.**
  When drafting your critical limits be specific in your language. Use action words, and be specific when naming people and equipment. An example could be "bake, uncovered in preheated 350ºF oven to an internal temperature of 165ºF for 15 seconds."

The HACCP team will find that many critical limits for your identified CCPs have already been established.

[In order to remain compliant with HACCP Final Rule you'll need scientific evidence to prove that these limits are effective or meet or exceed regulatory requirements. If your plant has a proven track record of producing safe products, it's likely that you are processing your food within the bounds of acceptable critical limits. You must have documentation to support this claim.]

In some cases you'll need more than one critical limit to control a particular hazard. For example, the typical critical limits for cooked beef patties are time/temperature, patty thickness, and conveyor speed. It is important that you identify all the critical limits for each of your products.

Making sure each CCP has preventive measures and critical limits is the responsibility of each establishment. The HACCP team may want to get help from outside HACCP experts when establishing their critical limits. Remember that the critical limits must be able to maintain control over the food safety hazard. Once the team has identified all the limits, enter them onto the Critical Limits form.

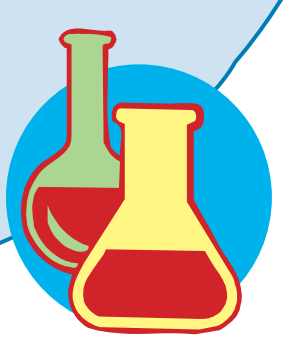
Take it to the Limit

Here are some controls commonly used as preventive measures.

- *Time & Temp.* - The temperature "*danger zone*" for biological hazards is between 40°F and 140°F. Bacteria grows fast! They have the ability to multiply rapidly. Knowing this shows that controlling how long the product is in the danger zone (if at all) presents itself as an extremely effective critical limit.

- *pH* - The pH of a food product is the level of its acidity or alkalinity. Acidity is measured on a scale of 0 to 14. The middle of the scale, pH=7.0, is considered neutral. Altering a food product's pH, such as adding an acidic substance like vinegar or soy sauce will decrease the growth rate of the bacteria.

- *Water Activity* - In addition to warm temperatures and a median pH, bacteria also need water to grow. Water Activity (A_W) refers to the amount of water in a food product that is available, or free, for bacteria to use for growth and multiplication. Solutes (salts and sugars), as well as dehydration, decrease the available water and can reduce bacterial growth.



Working with the "Critical Limits" Form

For each CCP the Example Plant has a separate page of critical limits.

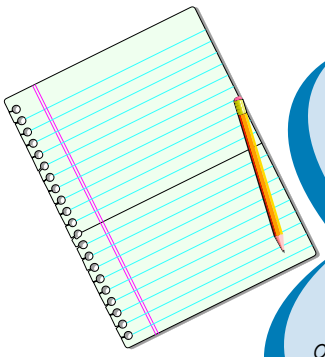
Under the "Limit" heading.

The Example Plant noted an internal temperature of 165°F for 15 seconds as the established critical limit. They then decided that the preventive measure of cooking at 190°F oven temperature for 3 hours would satisfy the critical limit.

Under the "Source" heading.

The Example Plant's first source is regulatory and scientific. They decided to take the established regulatory limits and use them, but then they also sent out samples of their finished product to be scientifically analyzed. The results of the lab tests confirmed that their critical limits were enough. The Example Plant's second source is their historical record. Since opening for business over 30 years ago, they never experienced a problem with bacterial contamination.

[The source is the "evidence" that backs up your critical limits. The source proves that the critical limit you cite will effectively control the food safety hazards. Sources for critical limits can be scientific, regulatory or historical. The HACCP team has to find at least one source for each of your critical limits, but you can always put more if you want.]



Documenting the Source

When determining your critical limits make sure you file your supporting documentation with your HACCP plan. This documentation will help validate that the limits have been properly established. These could be things such as letters from outside HACCP experts, or scientific reports, or lab test results. By holding onto these supporting documents you also provide verification material when needed.

HACCP Principle 3

Critical Limits Form

Product/Process Name: Beef Jerky

Process Step/CCP: Cooking CCP#01B

Critical Limits

Limit: - (Time, Temp., pH, etc.):

Internal temperature: 165 degrees Fahrenheit for 15 sec.

Preventive Measure: Oven temperature: 190 degrees Fahrenheit for 3 hours

Source: - (cite a regulation, scientific document, or other resource):

Microbiological analysis confirms effectiveness of our industry-standard approach.
Historically this critical limit has been adequate. (for over 20 years)

Developed by: Cindy Jones **Date:** 12/14/98

Principle 4: Establish Monitoring Procedures

Establish CCP monitoring requirements. Establish procedures for using the results of monitoring to adjust the process and maintain control.

Monitoring involves a series of observations and/or measurements that are used to make sure a CCP is under control. The HACCP team can think of monitoring activities as the checks-and-balances for each CCP's preventive measures. When someone monitors, they are "checking to see" that the critical limits are being met.

What are the three things monitoring can do for you?

Monitoring... shows you when a deviation from a critical limit has happened. For example, an employee tests the temperature of some frozen beef patties and discovers that the internal temperature has gone above the established critical limit of 40°F. If not caught here, this would be a potentially serious health risk to consumers.

Monitoring... helps you identify trends in your process that will allow you to predict a loss of control at a CCP. For example, a plant may monitor the temperature of a cold storage area at 6 a.m., 8 a.m., and 10 a.m. Each time, the temperature is within acceptable limits, but it is steadily climbing toward the high end of the range. This information points towards a trend, and the plant should take action to prevent the temperature from exceeding the critical limits.

Monitoring... produces written records for use in future HACCP plan verification steps. Written monitoring records will prove very valuable to your operation, should a serious problem along the production line occur. The records you keep prove that your company has established and carried out effective monitoring techniques.

Monitoring procedures can be thought of as **continuous** or **non-continuous**.

- *Continuous monitoring* is the constant monitoring of a critical control point.
- *Non-continuous monitoring* is the scheduled monitoring of a critical control point.

Continuous monitoring is always preferred when feasible. Continuous monitoring at a CCP is usually done with built-in measuring equipment, such as an automatic time-temperature thermostat used at a cooking step. This type of monitoring is preferred because it yields a permanent record. To make sure these activities stay accurate, you need to regularly check the monitoring equipment to make sure that it is calibrated correctly.

Keep This in Mind

When looking at your CCPs, think about the specific preventive measures you have chosen. Which method of monitoring will best keep track of the critical limits that need to be checked (i.e. time/temperature, pH, etc.)

If continuous monitoring isn't feasible for your CCP then the HACCP team will need to establish non-continuous monitoring procedures. Non-continuous doesn't mean random. The team should decide in the development phase what the monitoring schedule should be. When you use non-continuous monitoring, make sure that it's scheduled often enough to keep the food safety hazards under control. Expert advice from people with knowledge of practical statistics and stistical process control will be important in making your decisions. Types of non-continuous monitoring procedures include visual examinations, monitoring ingredient specifications, measurements of pH or water activity (A_W), taking product temperatures, and attribute sampling, etc.

[Something to keep in mind is a margin of safety. This margin can safely cover variations that might occur in your un-sampled products. For example, if your critical limit for cooking has been set at 160°F, your margin of safety might be to set the oven over 160°F. In this way you're prepared for variations that you might not have predicted.]

Who's Responsible?

Make sure to assign a specific person to be responsible for the monitoring of a CCP. The Example Plant has a designated shift leader/cook who is responsible for monitoring the cooking CCP. The person who actually does the monitoring must be the person who signs and dates all the records at the time of the monitoring.

In general, monitoring will go smoothly if the HACCP team:

- Clearly identifies the employee(s) responsible for monitoring.
- Trains the monitor in the proper testing procedures, the established critical limits, the methods of recording monitoring results, and the actions to be taken when critical limits are exceeded.
- Makes sure that the employee(s) understand the purpose and importance of monitoring.

The last step in establishing your monitoring procedures is to develop the Critical Limits and Monitoring Log(s) where the monitoring person will record the data for each CCP. Due to the variety of monitoring procedures, the HACCP team may need to develop different logs to record the monitoring data at different CCPs. When your HACCP system is up and running, you will use these logs to track the day-to-day HACCP activities. The simplest way to accomplish this is to use or modify the sample logs provided in Appendix A.

Working with the "Monitoring Procedures" Form

The form that is shown as an example on the next page is to be used as a tool in the *development of your HACCP plan*. The information on this form is the "Who, What, When, and How" of monitoring.

For the Example Plant:

- The *Who* is the cook on duty.
- The *What* is the temperature of the oven,
- The *When* is non-continuously – every 60 minutes, (± 5 minutes), and
- The *How* is with the oven temperature gauge.

The Example Plant felt this type of non-continuous monitoring would be effective because of the consistent heat environment of the oven. Their logic was that if the temperature taken at the beginning and end of the cooking cycle was the same, it could reasonably be assumed that it was okay for the whole cooking cycle.

Remembering your Monitoring

The key to effective and reliable monitoring is to keep it simple and build it into the employees' normal routines. When establishing a time for the actual monitoring procedure, allow some flexibility. For example, if you say you will monitor a CCP at 10 AM and the person is not there at exactly 10 AM, you could be opening yourself up for problems. It is sug- gested that you specify a period of time during which monitoring will occur. For example, write your time as "10 AM +/- 10 minutes" or "between the time period of 10 AM and 10:15 AM."

HACCP Principle 4

Monitoring Procedures Form

Product/Process Name: Beef Jerky

Process Step/CCP: Cooking CCP#01B

Monitoring Procedures - (Who, What, When, How)

The cook on duty records the oven temperature at 190°F at intervals of 60 minutes, (± 5 minutes) starting when a "lot" is placed in the oven and ending when the "lot" is removed from the oven. Each oven is monitored individually using oven temperature gauge.

Developed by: Cindy Jones **Date:** 12/14/98

Principle 5: Establish Corrective Actions

Establish corrective action to be taken when monitoring indicates that there is a deviation from an established critical limit.

The Final Rule defines a corrective action as **"*Procedures to be followed when a deviation occurs.*"** A deviation is defined as a **"*failure to meet a critical limit.*"**

Deviations *can and do* occur. After the HACCP team has established strict monitoring procedures, the next step is to draft corrective actions to be taken immediately when there is a loss of control at a CCP.

Corrective actions may include, but are not limited to the following:

1. Identifying and eliminating the cause of the deviation;

2. Demonstrating that the CCP is once again under control. *(This means examining the process or product again at that CCP and getting results that are within the critical limits)*;

3. Taking steps to prevent a recurrence of the deviation;

4. Making sure that no adulterated product enters commerce; and

5. Maintaining detailed records of the corrective actions.

If a deviation occurs that is not covered by a specific corrective action in your HACCP plan, or if some unforeseen hazard arises, appropriate steps should be taken. These steps shall include, but not be limited to:

1. Segregate and hold any affected product until its acceptability can be determined.

2. Determine the acceptability of the affected product for distribution.

3. Do not allow product that is injurious to health or is otherwise adulterated to enter commerce.

4. Reassess and, if necessary, modify your HACCP plan to properly address this type of deviation in the future.

5. Maintain detailed records of your actions.

Some examples of corrective actions are:

- Changing the process and holding the product for further evaluation.
- Empowering the monitoring personnel to stop the line when a deviation occurs. They should have the authority to hold all "lots" of a product not in compliance.
- Rely on an approved alternate process that can be substituted for the one that is out of control at the specific CCP.

Whatever type of corrective actions the HACCP team establishes, records for each one need to be kept that include:

- The deviation that was identified.
- The reason for holding the product, the time and date of the hold, the amount of product involved, and the disposition and/or release of product.
- The actions that were taken to prevent the deviation from recurring.
- The dated signature of the employee who was responsible for taking the corrective action.

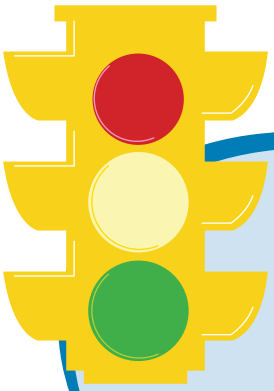
As with the monitoring logs, the HACCP team also needs to develop the log(s) for the corrective action results. Feel free to use the Deviation and Corrective Action Log in Appendix A "as-is," or modify it to suit your plant's needs.

Working with the "Corrective Action Procedures" Form

The Example Plant's corrective action form lays out exactly what they think should be done if a problem occurs with the CCP#01B.

- **Under the "Problem" heading.** *They state the critical limit that has been established for this CCP.*

- **Under the "Disposition of the Product" heading.** *If a deviation occurs, they have noted that the initial disposition would be to hold the product "lot," and try to rework it if possible. The "rework" would consist of fixing the temperature and re-cooking the jerky.*



Stopping the Line

The more ownership the employees feel they have in the HACCP system, the more effective they will be in ensuring that your plant produces safe food.

One idea is to empower the person responsible for monitoring to be able to stop the production line when and if a deviation occurs. This accomplishes two important functions:

- First, it prevents the potentially hazardous product from continuing down the production line.

- Second, it makes timely communication easier; thus you find out what's happening in your plant as soon as possible.

- **Under "Corrective Action Procedures/Steps" heading**
  As you can see, the Example Plant listed quite specific corrective actions for this CCP. Their directions are written concisely, and in the order they should be performed.

- **Under the "Who is Responsible" heading**
  They are specific in naming a particular person.

- **Under the "Retesting Procedures" heading**
  The Example Plant has projected that if this deviation happens at this CCP it will probably be because something went wrong with the thermostat in the oven. They list here what will probably need to be done to make sure this doesn't happen again. (If this deviation were to actually happen, the monitoring person would write on the corrective action log what he or she did to fix the problem, and what they did to make sure it wouldn't happen again.)

HACCP Principle 5
Corrective Action Procedures Form

Product/Process Name: Beef Jerky

Process Step/CCP: Cooking CCP #01B

Problem (critical limit exceeded):

Oven temp. below 190 degrees Fahrenheit

Disposition of Product: (Hold, Rework, Condemn)

Hold, rework if possible

Corrective Action Procedures / Steps:

1. Identify and segregate affected product, place on hold.
2. Rework if possible, otherwise condemn product: Reestablish correct cooking procedures (i.e. fix oven temp. settings, or move product to other oven for rework.)
3. Determine cause of deviation: broken oven thermostat
4. Take steps to prevent recurrence: recalibrate/replace thermostat
5. Notify Quality Control Supervisor a.s.a.p.

Who is responsible for taking these corrective actions?:

John Smith - Cook on duty

Retesting Procedure to Assure Compliance:

Recalibrate/Replace oven thermostat.
Monitor CCP as usual during rework.

Developed by: Cindy Jones **Date:** 12/14/98

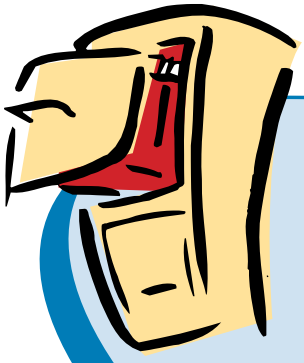
Principle 6: Establish Recordkeeping Procedures

Establish effective recordkeeping procedures that document the HACCP system.

The *records* you keep for HACCP can make all the difference! Good HACCP records - meaning that they are accurate and complete - can be a great help to you. Here's why:

- Records make it possible to trace ingredients, in-process operations, or finished products, should a problem occur.
- Records help you identify trends in your production line.
- Records can help you identify and narrow the scope of a product recall.
- Records serve as written documentation of your plant's compliance with HACCP regulations.

[Well-maintained records protect both your customers, and YOU!]



Record Retention & Storage

You are required to retain your HACCP records as follows:

- At least one year for slaughter activities
- At least one year for refrigerated products
- At least two years for frozen, preserved, or shelf-stable products.

All these records can take up a lot of space. After six months, you're allowed to keep all these records in storage as long as they can be retrieved and provided on site within 24 hours if an FSIS inspector requests to see them.

§ 417.5 Records.

" (a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis prescribed in § 417.2(a) of this part, including all supporting documentation;

(2) The written HACCP plan, including decisionmaking documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

(3) Records documenting the monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made…"

Your HACCP records should include your development forms and your daily logs for each CCP. You also need to keep your hazard analysis development forms, your CCP determination sheets, a list of critical limits for each food safety hazard, clear corrective action instructions, and a copy of your compiled HACCP plan. When first establishing your recordkeeping procedures, it's better to think of the different kinds of records you'll need in two ways.

First, there are records that are used for development and archival purposes; such as your Hazard Analysis, and your CCP decision making tool.

Second, there are records that you will work with on a day-to-day basis. These are the logs we've been discussing such as the monitoring or corrective action logs. As we've said before, the HACCP team will need to create these logs for each CCP in your process.

Regardless of the type of record, all HACCP records must contain at least the following information:

- *Title and date of record,*
- *Product identification,*
- *Critical limits,*
- *A line for the monitor's signature,*
- *A place for the reviewer's signature, and*
- *An orderly manner for entering the required data.*

Tips on Designing Records

One way to approach development of the recordkeeping requirements of your HACCP system is to review the records you already keep, and see if they are suitable, in their present form or with minor modifications, to serve the purposes of your HACCP system. The best recordkeeping system is usually the simplest one that can be easily integrated into the existing operation.

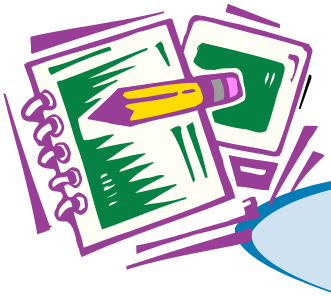
Working with the "Recordkeeping Procedures" Form

Under the "Records" heading.

You can see that the Example Plant has filled out their Recordkeeping Form making sure to list both the development forms (the hazard analysis), and the logs. (The logs have been circled in red.) Examples of the logs can be found in Appendix A.

[*One last note about the records you keep. When developing and working with your forms and logs remember to use ink (ballpoint pen) – no pencils! On all records, whenever you make a change, mark through the original and initial. Do not erase or mark the original so that it is unreadable.*]

Records Help You



Records help you demonstrate that your process is functioning well. By keeping accurate, up-to-date records, you help ensure safe products, satisfy the federal requirements, and protect your business.

HACCP Principle 6
Recordkeeping Procedures Form

Product/Process Name: Beef Jerky

Process Step/CCP: Cooking CCP #01B

Records:

Name and Location:

Name: Hazard Analysis Location: Office File Cabinet	Name: HACCP Plan Review Sheet - For each CCP Location: Oven Room Wall	Name: Monitoring Log For each CCP Location: Oven Room Wall
Name: Deviation / Corrective Action Log Location: Oven Room Wall	Name: Process-Monitoring Equipment Calibration Log - For each CCP Location: Oven Room Wall	Name: Verification Procedures & Results Log - For each CCP Location: Oven Room Wall

Developed by: Cindy Jones **Date:** 12/14/98

Principle 7: Establish Verification Procedures

Establish procedures to verify that the HACCP system is working correctly.

Your team needs to decide on what procedures the plant will perform to verify that the HACCP system is working effectively and how often these actions will be performed. Verification uses methods, procedures or tests in addition to those used in monitoring to see whether the HACCP system is in compliance with the HACCP plan or whether the HACCP plan needs modification. There are three types of verification. These are initial validation, ongoing verification, and reassessment of the HACCP plan.

Initial Validation

Validation is defined as ***"the scientific and technical process for determining that the CCPs and associated critical limits are adequate and sufficient to control likely hazards."*** The initial validation of your HACCP plan is the process by which your establishment proves that what is written in the HACCP plan will be effective in preventing, eliminating, or reducing food safety hazards. This validation activity is the exclusive responsibility of your establishment.

You carry out this validation by gathering evidence that supports your HACCP plan. The data you bring together can come from many sources. Such sources may include scientific literature, product testing results, regulatory requirements, and/or industry standards. Companies have a lot of flexibility in the compilation of this information in regards to the sources and the amount of such data.

[Most likely, you already have the majority of the validation information you need. When you conducted your hazard analysis and researched the sources for your critical limits, you were collecting data that could also be used to validate your entire HACCP plan.]

Ongoing Verification

Verification is ***"the use of methods, procedures, or tests in addition to those used in monitoring, to determine whether the HACCP system is operating as intended."*** After a HACCP plan has been initially validated and put into action, verification activities continue on an *ongoing* basis.

Simply stated, you need to verify that your HACCP system is working the way you expected. There are several ways to do this, here are a few: *(these aren't the only ones)*

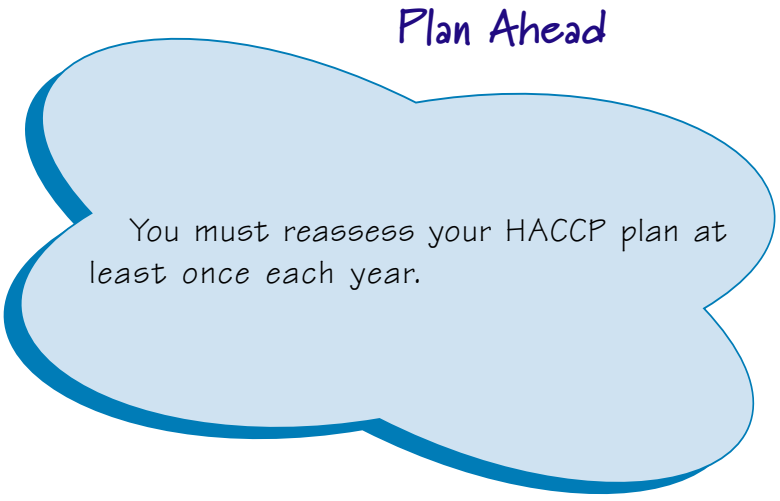
- Calibrate your monitoring equipment.
- Sample your product.
- Review your monitoring and corrective action logs.
- Personally inspect your plant's operations.

Whatever types of ongoing verification activities you decide to use, they should be included in your HACCP plan along with specifics on your CCPs, critical limits, monitoring, and corrective actions. Also, the HACCP team needs to identify the schedule for conducting the verification checks.

Reassessment of the HACCP Plan

The regulation 9 CFR 417.4(a)(3) states **"…Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan…"** Here are a few, but not all, specific changes that would require modification of your HACCP plan:

1. Potential new hazards are identified that may be introduced into the process.
2. New ingredients are added, or when an ingredient supplier is changed.
3. The process steps or procedures are changed.
4. New or different processing equipment is introduced.
5. Production volume changes.
6. The end point consumer for the product or the distribution system changes.
7. Personnel changes.



Your reassessment should include a review of the existing HACCP plan, including the product evaluation, hazard analysis, critical control points, critical limits, monitoring procedures, corrective actions and recordkeeping procedures.

Working with the "Verification Procedures" Form

It's important to remember that verification procedures are ongoing activities. For each CCP you will need a monitoring log, a deviation/corrective action log, and an equipment calibration log. These logs are the continual verification that HACCP is being done effectively. *(Examples of logs are located in Appendix A.)*

(Like the monitoring form in principle 4, the information on this form is the "Who, What, When, and How" of verification.)

For the Example Plant:

- The *Who* is the quality control supervisor,
- The *What* is each one of the four activities they need for their process,
- The *When* is specified after each activity, and
- The *How* would be determined as needed by the quality control supervisor.

HACCP Principle 7
Verification Procedures Form

Product/Process Name: Beef Jerky

Process Step/CCP: Cooking CCP #01B

Verification Procedures: - (Who, What, When, How)

- Thermometer calibration – Weekly
- Random observation of monitoring – Daily
- Review relevant records – Daily, prior to shipment
- Deviation response review – Ongoing
  - Responsible Plant Official

Developed by: Cindy Jones **Date:** 12/14/98

Finishing Your HACCP Plan

[One last note about your forms – Don't forget that each one needs to be reviewed in its entirety and signed and dated by the responsible establishment official on the HACCP team. This person will make sure that all the pages of the HACCP plan are signed and dated. This assures the team that only the most complete and up-to-date plan is being used.]

The HACCP system produces real results. HACCP is a way of getting and keeping control over your entire production process.

It's extremely important that your sanitation SOPs (SSOPs) are in place before you start implementing HACCP. You probably already follow these practices on a daily basis. These procedures are essential building blocks for an effective HACCP plan.

Building Blocks

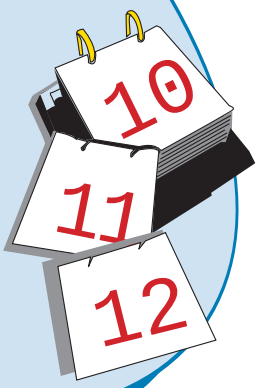
Building your HACCP system begins when the HACCP team comes together. Your HACCP plan is built one step at a time. In sections 3 and 4 you learned how each HACCP step builds on the ideas and information of the previous step. For example, you can't successfully identify all of the food safety hazards in your process (Principle 1) if you don't have a thorough raw materials and ingredients list. Likewise, you can't correctly pinpoint all of your CCPs (Principle 2) if you don't have an accurate flow diagram.

The deadline for very small plant implementation of HACCP is January 25, 2000. When thinking about your HACCP system implementation, be careful to give yourself enough time before the deadline. If you choose to wait until the last minute and implement rapidly, or all at once, the number of different things that can occur, and that could go wrong, will frustrate you. Your chances of identifying any widespread problems will be less, and managing the process could become harder than it really is. **Don't make this mistake - successful implementation requires time.**

Suggested Order of Events

Very small plants planning to meet HACCP requirements should begin the first step in developing a HACCP plan by June 1999, or as early as possible. The person responsible for developing the plan could break the entire process into a few steps such as the following:

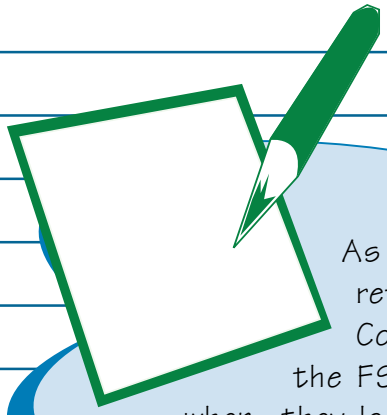
1. Complete HACCP training or complete this self-study program.
    a. Start hazard analyses in three steps:
        1. draft and verify product flow diagram
        2. identify potential hazards
        3. select critical control points
    b. Set critical limits for CCPs and establish corrective actions.
    c. Prepare a recordkeeping system for monitoring CCPs.
    d. Select verification procedures.
    e. Write HACCP plan(s).
2. Train employees to use the HACCP system.
3. Implement your HACCP plan by January 25, 2000.



Where to Get More Information

- HACCPWORKS: (877) 422-2799
  Web site: http://www.tteam.com/haccpworks/
  e-mail: haccpwx@tteam.com
- FSIS Web site: http://www.usda.gov/fsis/
- FSIS Technical Service Center (800) 233-3935
- USDA Meat and Poultry Hotline (800) 535-4555
- Office of the FSIS National HACCP Small Plant Coordinator (202) 720-3219
- National Agriculture Library/USDA
  (301) 504-6365; fax: (301) 504-6409
  e-mail: foodborne@nal.usda.gov
- International Meat and Poultry HACCP Alliance (409) 862-2036
  Web site: http://ifse.tamu.edu/haccpall.html

Notes



Inspector's Checklist

As you build your HACCP Plan, a good reference to keep in mind is the "Basic Compliance Checklist." This list will tell you what the FSIS inspectors will be specifically looking for when they look at your HACCP system to see if the basic requirements are met. A copy of this document can be found in Appendix B.

Notes

Review Questions

[The answers to these Review Questions are in Section 5.]

1. Complete the following statement: HACCP Principle #6 states, "Establish effective recordkeeping procedures that _____ ."

a.) Control the HACCP system
b.) Justify the HACCP system
c.) Document the HACCP system
d.) Outline the HACCP system

2. Which of the following are common types of foodborne physical hazards?

a.) Hormonal residues, sanitizers, pesticides and antibiotics
b.) Glass, metal, bone and plastic
c.) Bacteria, molds, yeast and parasites
d.) Bacteria, metal, sanitizers and plastic

3. Methods, procedures, and tests used to determine if the HACCP system in use is in compliance with the HACCP plan are known as:

a.) Verification
b.) Recordkeeping
c.) Documentation
d.) Validation

4. In what step do you list information about potential hazards that are controlled, introduced, or enhanced in the process?

a.) HACCP Principle 1
b.) HACCP Principle 2
c.) HACCP Principle 3
d.) HACCP Principle 4

5. Monitoring records:

a.) Have little historical value.
b.) Have little value in determining trends.
c.) Need not be signed by the actual person doing the monitoring.
d.) Should be completed and signed or initialed at the time of monitoring

6. Validation records:

a.) Must be more realistic than scientific.
b.) Must be based on science.
c.) Are of little value in the verification process.
d.) Require the signature of the specific process operator.

7. It is important that the firm reassess the HACCP plan:

a.) At least once per year
b.) Every 6 months
c.) Monthly
d.) Every 45-60 days

8. What are the general categories of hazards that a HACCP program should control?

a.) Physical, Environmental, Chemical
b.) Biological, Chemical, Physical
c.) Pre-existing, Induced
d.) Natural, Man-made

9. A point in a process where loss of control could result in an adulterated product is called a(n):

a.) Critical Control Process
b.) Quality Control Point
c.) Critical Control Point
d.) Critical Limit Process

10. Validation differs from verification in that:

a.) Verification determines if the HACCP system is in compliance with the HACCP plan; validation is the initial review to make sure the HACCP plan works.
b.) Verification determines if the HACCP plan must be validated.
c.) All the above
d.) None of the above

Section 5

Review Question - Answers

Answers to Section 3 Review Questions

1. d.

The questions you should ask about your product are as follows:

1. Common name?
2. How will this product be used?
3. The type of package?
4. Length of shelf life?
5. Where will it be sold?
6. Labeling instructions?
7. Is special distribution control needed?

2. c.

When the flow diagram is complete, the HAACP team should conduct a "walk-through" to verify that the steps listed on the diagram are a good description of what occurs on the production line.

3. c.

Your HACCP team is responsible for building the HACCP plan. The team members will also be responsible for passing HACCP information on to other employees, because the HACCP team will be the ones who have the depth of knowledge to do this.

4. a.

The purpose of finishing the preliminary steps is to gather information. Creating and verifying the flow diagram are a part of the preliminary steps. It is not necessary to hire a consultant to approve your flow diagram. Educating all employees in the 7 HAACP principles is not a part of the preliminary steps.

5. c.

Once each form is completed it should be signed and dated.

6. c.

Very small plants may have only one or two people who are qualified for the team. HACCP is VERY important to all small food production plants.

7. c.

The flow diagram must be easy to follow and show all of the steps in your production process. It doesn't need to be approved by FSIS. Information about your product is provided in the Product/Process Description. There is no "supporting information" that must be a part of the flow diagram.

Answers to Section 4 Review Questions

1. c.

Your records should document your HACCP system. They are your proof that your system is working.

2. b.

Glass, metal, bone and plastic are common types of foodborne physical hazards.

3. a.

Verification entails the use of methods, procedures, or tests in addition to those used in monitoring, to determine whether the HACCP system is operating as intended.

4. a.

HACCP Principle 1 states, "Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur and describe the preventive measures."

5. d.

Monitoring records, just like all HACCP records, should be signed or initialed and dated by the person responsible at the time of the monitoring. They also have a very high historical value and are necessary for determining trends.

6. b.

Validation records are what your establishment will use to demonstrate that what is written in the HACCP plan and implemented in the establishment actually prevents, eliminates or reduces food safety hazards. These records should be scientific, and they are useful in the verification process.

7. a.

You should reassess your HACCP plan at least once a year. Also:

- When potential new hazards are identified that may be introduced into the process.
- When new ingredients are added, or when an ingredient supplier is changed.
- When the process steps or procedures are changed.
- When new or different processing equipment is introduced.
- When production volume changes.
- When the end point consumer for the product or the distribution system changes.
- When personnel changes.

8. b.

The three types of hazards are: biological, chemical, and physical.

9. c.

The definition of a Critical Control Point is: "A point, step or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated or reduced to acceptable levels."

10. a.

Verification determines if the HACCP system is operating as intended. Verification occurs on an ongoing basis. Validation demonstrates that the HACCP plan is adequate and sufficient to control likely food safety hazards. Validation is performed as the HACCP plan is first implemented.

Appendices

Appendix A-
Blank Development Forms & Logs

HACCP Plan Development Forms

Company: _____

Address: _____

City, State,
Zip Code: _____

Phone: _____

Fax Number: _____

Contact Person: _____

Comments: _____

_____

_____

_____

Developed by: _____ **Date:** _____

Step 1

HACCP Team Form

Team Members	Role

Developed by: _____ **Date:** _____

Step 2

Product/Process Description Form

1. Common Name?

2. How will this product be used?

3. Type of package?

4. Length of shelf life? At what temperature?

5. Where will be sold?

6. Labeling instructions?

7. Is special distribution control needed?

Developed by: _____ **Date:** _____

Step 3

Ingredients & Raw Materials Form

Product/Process Category: _____

Product/Examples: _____

Meat/Poultry and Byproducts	Nonmeat Food Ingredients	Binders/ Extenders
Spices/ Flavorings	**Restricted Ingredients**	**Preservatives/ Acidifiers**
Liquid	**Packaging Materials**	**Other**

Developed by: _____ **Date:** _____

Steps 4 & 5

Flow Diagram Development & Verification Form

Product/Process Name: _____

Flow Diagram:

Developed by: _____ Date: _____

Verified by: _____ Date: _____

HACCP Principle 1
Hazard Analysis Form

Product/Process Name: _____

Process Step from Flow Diagram: _____

Food Safety Hazard Analysis -

C: Chemical	B: Biological	P: Physical
List the Hazards:		
Is the Hazard *Reasonably Likely to Occur*? Yes / No		
What is the basis for your decision?		
What Preventive Measures can be applied at this step to *Prevent*, *Eliminate*, or *Reduce* the hazard to an acceptable level?		

Developed by: _____ **Date:** _____

HACCP Principle 2: Identifing Critical Control Points

Critical Control Point Decision Tree
for the production of cooked products

Process/Step: _____

Question 1a

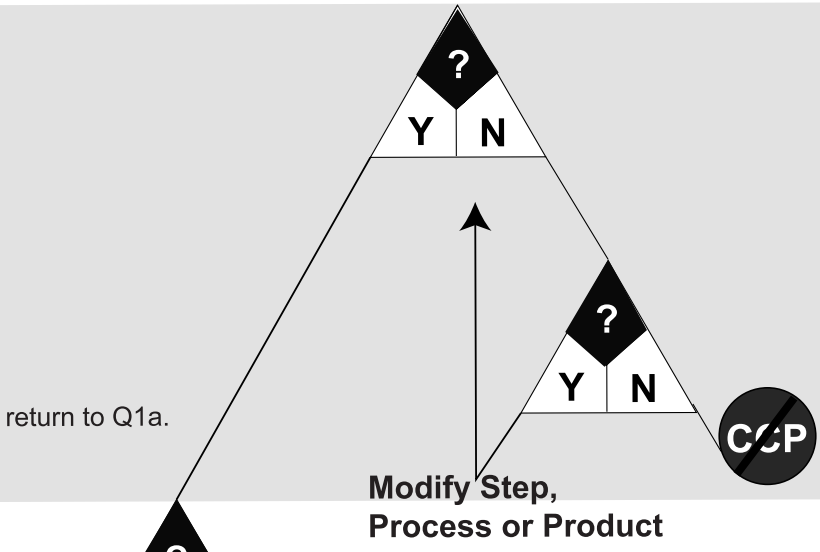
Do preventive measures exist for the identified hazard(s)?

If no - go to Q1b.
If yes - go to Q2.

Question 1b

Is control at this step necessary for safety?

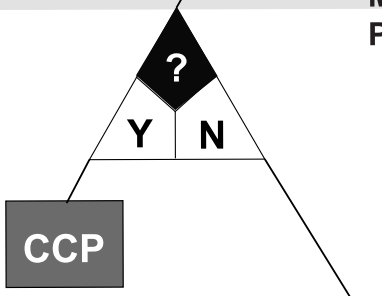
If no - not a CCP
If yes - modify step, process or product and return to Q1a.



Question 2

Does this step eliminate or reduce the likely occurence of a hazard(s) to an acceptable level?

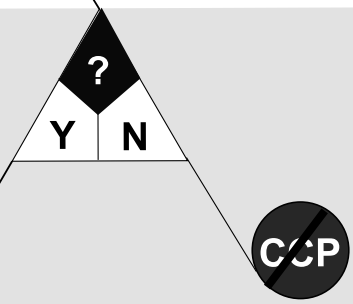
If no - go to Q3.
If yes - CCP.



Question 3

Could contamination with identified hazard(s) occur in excess of acceptable levels or could these increase to unacceptable levels?

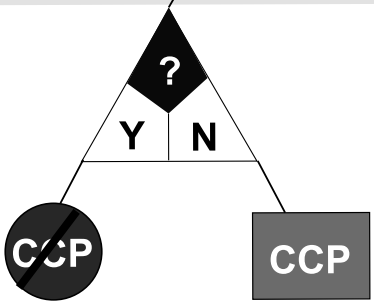
If no - not a CCP.
If yes - go to Q4.



Question 4

Will a subsequent step eliminate the identified hazards or reduce the likely occurence to an acceptable level?

If no - CCP.
If yes - not a CCP.



RESULTS:

BIOLOGICAL	CHEMICAL	PHYSICAL
☐ CCP # ____	☐ CCP # ____	☐ CCP # ____
☐ Not a CCP	☐ Not a CCP	☐ Not a CCP

Developed by: _____ **Date:** _____

HACCP Principle 3

Critical Limits Form

Product/Process Name: _____

Process Step/CCP: _____

Critical Limits

Limit: - (Time, Temp., pH, etc.):

Source: - (cite a regulation, scientific document, or other resource):

Developed by: _____ **Date:** _____

HACCP Principle 4

Monitoring Procedures Form

Product/Process Name: _____

Process Step/CCP: _____

Monitoring Procedures - (Who, What, When, How)

Developed by: _____ **Date:** _____

HACCP Principle 5

Corrective Action Procedures Form

Product/Process Name: _____

Process Step/CCP: _____

Problem (critical limit exceeded):

Disposition of Product: (Hold, Rework, Condemn)

Corrective Action Procedures / Steps:

Who is Responsible for Performing these Corrective Actions?:

Retesting Procedure to Assure Compliance:

Developed by: _____ **Date:** _____

HACCP Principle 6

Recordkeeping Procedures Form

Product/Process Name: _____

Process Step/CCP: _____

Records:

Name and Location:

Developed by: _____ **Date:** _____

HACCP Principle 7

Verification Procedures Form

Product/Process Name: _____

Process Step/CCP: _____

<u>Verification Procedures</u> - (Who, What, When, How)

Developed by: _____ **Date:** _____

PRE-SHIPMENT HACCP RECORDS VERIFICATION

The shipping clerk will check all HACCP Recor
with each lot of product prior to shipment f
and proper corrective action if

Date/Time	Product/ID #	CCP #	Deviation	Corrective Action	Records Complete Yes	Records Complete No	Initials

DATE: _____ MONITOR: _____

DATE: _____ VERIFICATION : _____

CCP Verification Log

PRODUCT: _____ BRAND: _____

EST NO: _____ DATE: _____ REVISION NO:_____

PLANT: _____ PREPARED BY: _____

PROCESS STEP CCP	VERIFICATION PROCEDURES			
	WHO	WHAT	WHEN	RESULTS

DATE: _____ MONITOR: _____

DATE: _____ VERIFICATION :_____

Time/Temperature Monitoring Log

Date	Product Description ID/Code	Time In	Time Out	Temperature	Accept/ Reject	Corrective Action	Monitor's Initials/ Time/Date	Verified By Initials/ Time/Date

Verified By: _____ **Date:** _____

Fermentation Monitoring Log

Date	Product Description ID/Code	Time In	Time Out	Temperature	pH	Comments	Monitor's Initials/ Time/Date	Verified By Initials/ Time/Date

Verified By: _____ **Date:** _____

Primal Cold Storage Monitoring Log

Date	Product Description ID/Code	Time In	Time Out	Room Temperature	Corrective Action	Monitor's Initials/ Time/Date	Verified By Initials/ Time/Date

Verified By: _____ **Date:** _____

Final Product Cold Storage Monitoring Log

Date	Product Description ID/Code	Time In	Time Out	Room Temperature	Corrective Action	Monitor's Initials/ Time/Date	Verified By Initials/ Time/Date

Verified By: _____ **Date:** _____

Appendix B-
HACCP Systems Basic Compliance Checklist

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

HACCP SYSTEMS BASIC COMPLIANCE CHECKLIST

ESTABLISHMENT NAME	ESTABLISHMENT NO.	PROCESS

PRODUCTS COVERED BY PROCESS

IMPLEMENTATION DATE	NEW PRODUCT	REASSESSMENT DATE *(Yearly: Check for dated signature only)*

Use this checklist to document findings of noncompliance with the requirements set out in FSIS Directive 5000.1, Part Two, Paragraph II.B.

1. HAZARD ANALYSIS AND HACCP PLAN DEVELOPMENT

REQUIREMENT	YES (✓)
INITIAL HAZARD ANALYSIS (§ 417.2 (a))	
The establishment has not conducted a hazard analysis or had a hazard analysis conducted for it.	
The hazard analysis	
does not include food safety hazards that are reasonably likely to occur in the production process, or	
does not identify the preventive measures the establishment can apply to those food safety hazard (s)	
The hazard analysis does not include a flow chart that describes (diagrams) the steps of each process and product flow in the establishment.	
The hazard analysis does not identify the intended use or consumers of finished product (s).	
INITIAL PLAN DEVELOPMENT (§ 417.2 (c) (4), § 417.3 (a) (2), and § 417.4 (a) (1))	
The establishment's hazard analysis revealed one or more food safety hazards that are reasonably likely to occur, and the establishment does not have a written HACCP plan for each of its products (§ 417.2 (b) (1); § 304.3 (c) or § 381.22 (c)).	
The establishment has not conducted validation activities to determine that a HACCP plan is functioning as intended.	
The establishment's records do not include	
multiple results that verify the monitoring of CCP's and conformance with critical limits, or	
after a deviation from a critical limit (if any), subsequent results that support the adequacy of corrective action (s) in achieving control at the CCP.	
SUBSEQUENT ANALYSIS AND PLAN DEVELOPMENT	
HAZARD ANALYSIS REASSESSMENT	
After an establishment's hazard analysis revealed no food safety hazards that are reasonably likely to occur, there was a change that could reasonably effect whether a food safety hazard exists, the establishment did not reassess the adequacy of the hazard analysis (§ 417.4 (b)).	
NEW PRODUCT (§ 304.3 (c) or § 381.22 (c))	
(1) Before producing new product for distribution, the establishment did not conduct a hazard analysis (or have a hazard analysis conducted for it), or	
did not have an applicable HACCP plan for the product.	
(2) The establishment began distributing a new product more than 90 days ago, and it has not validated the HACCP plan that covers the new product.	

FSIS FORM 5000-1 (9/97)

55

FSIS FORM 5000-1 (REVERSE)

	REQUIREMENT	YES (✓)
2. CONTENTS OF HACCP PLAN (S)	**MULTIPLE PRODUCTS** A HACCP plan covers more than one product and the products are not all within one of the nine processing categories specified in § 417.2 (b) (1), § 417.2 (b) (2).	
	FOOD SAFETY HAZARD (S) The HACCP plan does not list the food safety hazard (s) identified in the hazard analysis (§ 417.2 (c) (1)). (Exception: A HACCP plan for thermally processed/commercially sterile products produced in accordance with part 318, subpart G, or part 381, subpart X, need not address food safety hazards associated with microbiological contamination (§ 417.2 (b) (3)).)	
	HAZARD CONTROL The HACCP plan does not list CCP's for each food safety hazard (§ 417.2 (c) (2)).	
	The HACCP plan does not list critical limits to be met at each CCP (§ 417.2 (c) (3)).	
	MONITORING The HACCP plan does not list the procedures to be used to monitor each CCP and the frequency with which these procedures will be performed (§ 417.2 (c) (4)).	
	CORRECTIVE ACTIONS The HACCP plan does not identify the corrective action to be followed in response to a deviation from a critical limit at a CCP (§ 417.2 (c) (5)).	
	VERIFICATION PROCEDURES The HACCP plan does not list the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequency with which these procedures will be performed (§ 417.2 (c) (7)).	
3. RECORDKEEPING	The HACCP plan's recordkeeping system does not document the monitoring of CCP's and/or does not include records with the actual values and observations (§ 417.2 (c) (6)).	
4. ...ATED SIGNATURE	**ACCEPTANCE AND REASSESSMENT** (§ 417.2 (d)) The responsible establishment official did not sign and date the HACCP plan (1) upon initial acceptance, or	
	(2) at least annually thereafter upon required plan reassessment.	
	MODIFICATION The HACCP plan was modified, and the responsible establishment official did not sign and date the plan (§ 417.2 (d) (2) (ii)).	

56

Appendix C-
Regulations 9 CFR Part 417

PART 417—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

Sec.

Authority: 7 U.S.C. 450; 21 U.S.C. 451-470, 601-695; 7 U.S.C. 1901-1906; 7 CFR 2.18, 2.53.

Sec. 417.1 Definitions.

For purposes of this part, the following definitions shall apply:

Corrective action. Procedures to be followed when a deviation occurs.

Critical control point. A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical limit. The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Food safety hazard. Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

HACCP System. The HACCP plan in operation, including the HACCP plan itself.

Hazard. SEE Food Safety Hazard.

Preventive measure. Physical, chemical, or other means that can be used to control an identified food safety hazard.

Process-monitoring instrument. An instrument or device used to indicate conditions during processing at a critical control point.

Responsible establishment official. The individual with overall authority on-site or a higher level official of the establishment.

Sec. 417.2 Hazard Analysis and HACCP Plan.

(a) Hazard analysis. (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.

(2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.

(3) Food safety hazards might be expected to arise from the following:

(i) Natural toxins;

(ii) Microbiological contamination;

(iii) Chemical contamination;

(iv) Pesticides;

(v) Drug residues;

(vi) Zoonotic diseases;

(vii) Decomposition;

(viii) Parasites;

(ix) Unapproved use of direct or indirect food or color additives; and

(x) Physical hazards.

(b) The HACCP plan. (1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:

(i) Slaughter—all species.

(ii) Raw product—ground.

(iii) Raw product—not ground.

(iv) Thermally processed—commercially sterile.

(v) Not heat treated—shelf stable.

(vi) Heat treated—shelf stable.

(vii) Fully cooked—not shelf stable.

(viii) Heat treated but not fully cooked—not shelf stable.

(ix) Product with secondary inhibitors—not shelf stable.

(2) A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.

(3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of part 318, subpart G, or part 381, subpart X, of this chapter.

(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum:

(1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.

(2) List the critical control points for each of the identified food safety hazards, including, as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and

(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;

(3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;

(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include all corrective actions that have been developed in accordance with Sec. 417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point; and

(6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with Sec. 417.4 of this part.

(d) Signing and dating the HACCP plan. (1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the

establishment accepts and will implement the HACCP plan.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) At least annually, upon reassessment, as required under Sec. 417.4(a)(3) of this part.

(e) Pursuant to 21 U.S.C. 608 and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in accordance with the requirements of this part, may render the products produced under those conditions adulterated.

Sec. 417.3 Corrective actions.

(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

(1) The cause of the deviation is identified and eliminated;

(2) The CCP will be under control after the corrective action is taken;

(3) Measures to prevent recurrence are established; and

(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

(b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform a review to determine the acceptability of the affected product for distribution;

(3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;

(4) Perform or obtain reassessment by an individual trained in accordance with Sec. 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

(c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with Sec. 417.4(a)(2)(iii) and the recordkeeping requirements of Sec. 417.5 of this part.

Sec. 417.4 Validation, Verification, Reassessment.

(a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.

(1) Initial validation. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

(2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:

(i) The calibration of process-monitoring instruments;

(ii) Direct observations of monitoring activities and corrective actions; and

(iii) The review of records generated and maintained in accordance with Sec. 417.5(a)(3) of this part.

(3) Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with Sec. 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of Sec. 417.2(c) of this part.

(b) Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

Sec. 417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis prescribed in Sec. 417.2(a) of this part, including all supporting documentation;

(2) The written HACCP plan, including decisionmaking documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

(3) Records documenting the monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with Sec. 417.7 of this part, or the responsible establishment official.

(d) Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(e) Record retention. (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.

(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.

(f) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

Sec. 417.6 Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

(a) The HACCP plan in operation does not meet the requirements set forth in this part;

(b) Establishment personnel are not performing tasks specified in the HACCP plan;

(c) The establishment fails to take corrective actions, as required by Sec. 417.3 of this part;

(d) HACCP records are not being maintained as required in Sec. 417.5 of this part; or

(e) Adulterated product is produced or shipped.

Sec. 417.7 Training.

(a) Only an individual who has met the requirements of paragraph

(b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:

(1) Development of the HACCP plan, in accordance with Sec. 417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product; and

(2) Reassessment and modification of the HACCP plan, in accordance with Sec. 417.3 of this part.

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

Sec. 417.8 Agency verification.

FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:

(a) Reviewing the HACCP plan;

(b) Reviewing the CCP records;

(c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;

(d) Reviewing the critical limits;

(e) Reviewing other records pertaining to the HACCP plan or system;

(f) Direct observation or measurement at a CCP;

(g) Sample collection and analysis to determine the product meets all safety standards; and

(h) On-site observations and record review.

Done at Washington, DC, on: July 5, 1996.
Michael R. Taylor,
Acting Under Secretary for Food Safety.


brought to you by
HACCPWORKS